FINDING OF NO SIGNIFICANT IMPACT

Environmental Assessment of U.S. Army Medical Research Institute of Infectious Diseases

1. PROPOSED ACTION: The proposed action (preferred alternative) and subject of this Environmental Assessment (EA) is continuing the current and currently planned activities at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) located at Fort Detrick in Frederick, Maryland. USAMRIID currently conducts research to develop strategies, products, information, procedures, and training programs for medical defense against validated biological warfare threats and infectious diseases. Studies are conducted on the pathogenesis, diagnosis, prophylaxis, treatment, and epidemiology of infectious diseases and toxins. In many instances, the disease-causing organisms require biological containment facilities to ensure the safety of workers and the environment. USAMRIID is a principal participant in the biological defense research program of the Department of Defense. The EA is incorporated by reference in this Finding of No Significant Impact (FNSI).

2. ALTERNATIVES CONSIDERED: During the preparation of this EA, two alternatives to the proposed action were identified. These alternatives are: to conduct some or all of the current and currently planned USAMRIID activities at another facility (Alternative II); and to cease current and currently planned activities at USAMRIID (Alternative III, no action). This EA characterizes the reasonably predictable environmental impacts, including impacts to human health, that might result from continuing current and currently planned activities at USAMRIID (Alternative I, the preferred alternative) or the other alternatives considered.

3. ENVIRONMENTAL CONSEQUENCES AND MITIGATION MEASURES: It is unlikely that significant adverse environmental impacts will result from implementing the proposed action or the alternatives. The preferred alternative includes continuing to mitigate potential risks to human health and the environment by applying required standards, practices, and controls pertaining to the safe use and disposal of hazardous biological and chemical materials, the protection and conservation of natural resources, and the safe and ethical conduct of laboratory and animal studies, as well as the use of human volunteers. The most severe potential effects associated with the proposed action are predicted to be negligible, and, to date, all quantifiable impacts associated with similar activities at USAMRIID have been insignificant.

4. FACTORS CONSIDERED IN THE FINDING OF NO SIGNIFICANT IMPACT: The EA systematically reviews the nature of the proposed action and associated risks and issues. Particular attention is given to safety of the workforce and surrounding community. The alternatives are evaluated with regard to needs of the U.S. and the Department of the Army, and potential adverse effects on the environment.

5. CONCLUSIONS: The principal conclusions of this EA are: (1) continuing current and currently planned activities at USAMRIID (Alternative I, the preferred alternative) is not expected to result in significant adverse environmental impacts; (2) implementing the preferred alternative will likely result in important benefits to the U.S. by contributing to medical defense against validated biological warfare threats and infectious diseases; (3) conducting some or all of the current and currently planned USAMRIID activities at another facility (Alternative II) is not likely to alter the negligible to minor potential for environmental impact and does not offer significant advantage over the preferred alternative; and (4) ceasing current and currently planned activities at USAMRIID (Alternative III, no action) will eliminate the negligible environmental impacts associated with the proposed action, but will also impede U.S. efforts toward medical defense against validated biological warfare threats and infectious diseases.

JOHN S. PARKER
Major General, MC
Commanding

Comments on this FNSI may be directed to Headquarters, USAMRMC, ATTN: MCMR-PA (Chuck Dasey), 504 Scott Street, Fort Detrick, MD 21702-5012, and must be received by July 5, 2001. Copies of the EA are available for review at the Post Library, 1520 Freedman Drive / Suite 300 / Room 143, Fort Detrick, Frederick, MD 21702; the Frederick County Public Library, C. Burr Artz Central Library, 5340 Spectrum Drive, Suite A, Frederick, MD 21703; and at http://MRMC-www.army.mil. Copies of the EA may be obtained by writing to Mr. Dasey at the address above.

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ENVIRONMENTAL ASSESSMENT
OF
U.S. ARMY MEDICAL RESEARCH INSTITUTE
OF INFECTIOUS DISEASES

June 2001

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Environmental Assessment
of
U.S. Army Medical Research Institute of Infectious Diseases

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June 2001

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EXECUTIVE SUMMARY

This Environmental Assessment (EA) was prepared in accordance with guidance provided in Army Regulation (AR) 200-2, *Environmental Effects of Army Actions*, dated December 23, 1988, and the *Council on Environmental Quality (CEQ) Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act (NEPA)* (40 Code of Federal Regulations [CFR] 1500-1508). This EA, *Environmental Assessment of U.S. Army Medical Research Institute of Infectious Diseases*, was prepared by the U.S. Army Medical Research and Materiel Command (USAMRMC) with assistance from Science Applications International Corporation (SAIC) and its subcontractor, BSA Environmental Services, Inc., under Contract Number DAMD17-98-D-022.

This EA describes and analyzes the potential adverse environmental impacts, including human health impacts, associated with continuing the current and currently planned activities at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) located at Fort Detrick in Frederick, Maryland. Any contemplated or likely action is considered a proposed activity whether or not it actually materializes. This analysis considers impacts expected from continuing the current and currently planned USAMRIID activities, cumulative impacts that might occur after several years, impacts resulting from association with other activities in the area, and impacts resulting from an accident or incident.

During the preparation of this EA, two alternatives to the proposed action were identified. These alternatives are: to conduct some or all of the current and currently planned USAMRIID activities at another facility (Alternative II); and to cease current and currently planned activities at USAMRIID (Alternative III). This EA characterizes the reasonably predictable environmental impacts, including impacts to human health, that might result from continuing current and currently planned activities at USAMRIID (Alternative I, no action, the preferred alternative) or the other alternatives considered.

The principal conclusions of this EA are: (1) continuing current and currently planned activities at USAMRIID (Alternative I, no action, the preferred alternative) is not expected to result in significant adverse environmental impacts; (2) implementing the preferred alternative will likely result in important benefits to the U.S. by contributing to medical defense against validated biological warfare threats and infectious diseases; (3) conducting some or all of the current and currently planned USAMRIID activities at another facility (Alternative II) is not likely to alter the negligible to minor potential for environmental impact and does not offer significant advantage over the preferred alternative; and (4) ceasing current and currently planned activities at USAMRIID (Alternative III) will eliminate the negligible environmental impacts associated with the proposed action, but will also impede U.S. efforts toward medical defense against validated biological warfare threats and infectious diseases.

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1.0 PURPOSE AND NEED FOR CONTINUATION OF ACTIVITIES AT USAMRIID

The proposed action (Alternative I, no action, preferred alternative) and subject of this Environmental Assessment (EA) is continuing the current and currently planned activities at the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID) located at Fort Detrick in Frederick, Maryland. USAMRIID currently conducts unclassified research to develop strategies, products, information, procedures, and training programs for medical defense against validated biological warfare threats and infectious diseases. The Defense Threat Reduction Agency (DTRA), through Headquarters, U.S. Army Medical Research and Materiel Command (HQ, USAMRMC) funds programs at this facility to implement various aspects of its biological defense research program (BDRP). Similarly, the Department of the Army (DA) through HQ, USAMRMC sponsors research and development at USAMRIID, a subordinate laboratory of USAMRMC, for discovery and development of medical protection and treatments against military relevant infectious diseases.

Studies are conducted on the pathogenesis, diagnosis, prophylaxis (prevention), treatment, and epidemiology of infectious diseases and toxins. In many instances, the disease-causing organisms (e.g., bacteria, viruses, and rickettsia) require biological containment facilities to ensure the safety of workers and the environment. Drugs and vaccines as well as diagnostic capabilities, and medical management procedures are among the medical products and systems developed to preserve the fighting strength of U.S. soldiers. Vaccine development may involve the use of etiologic agents (i.e., any viable microorganism or its toxin that causes, or may cause, human disease) that require the use of laboratories, procedures, and associated expertise for achieving biological containment at biosafety levels 3 and 4 (BSL-3 and BSL-4). USAMRIID is a principal participant in the BDRP of the Department of Defense (DoD). A primary objective of the BDRP is the development of products and systems to medically protect military personnel against potential biological weapons attack. A detailed description of USAMRIID activities is found in Section 2.0 of this EA.

In accordance with the National Environmental Policy Act (NEPA) (42 U.S. Code [USC] 4321-4347), each Federal agency must consider the potential environmental impacts associated with proposed major actions. The Council on Environmental Quality (CEQ), Executive Office of the President, has promulgated regulations implementing NEPA (40 Code of Federal Regulations [CFR] 1500-1508). Army Regulation (AR) 200-2, *Environmental Effects of Army Actions*, dated December 23, 1988 (32 CFR 651), is the DA's implementation of NEPA and the CEQ regulations. This EA was prepared in accordance with CEQ regulations and AR 200-2.

To reduce redundancy with previous relevant documents as required by the CEQ (40 CFR 1500-1508), this EA is tiered, in part, to earlier NEPA documentation. This approach entails referencing specific analyses, discussions, and conclusions of these documents without providing detailed discussion in the current EA. Consistent with CEQ guidance and DA policy (AR 200-2, paragraph 2-6e), the EA is tiered to the *Environmental Assessment, United States Army Medical Research Institute of Infectious Diseases* dated July 1991 (USAMRIID, 1991), the *Installation Environmental Assessment (Fort Detrick)* (Installation EA) dated February 1991 (DA, 1991), and the *Environmental Planning Guide for Fort Detrick, Frederick, Maryland* (EPG) (U.S. Army Garrison [USAG], 1998) and the *Biological Defense Research Program Final Programmatic Environmental Impact Statement* (BDRP FPEIS) dated 1989 (DA, 1989).

This EA describes and analyzes the potential adverse environmental impacts, including human health impacts, associated with conducting the proposed activities. This EA also considers the impacts anticipated from the continuing current and currently planned activities at USAMRIID, the cumulative impacts that might occur after several years, the impacts resulting from association with other activities in the area, and the impacts that might result from an accident or incident. Two alternatives to the proposed action are also evaluated (see Sections 3.0 and 5.0).

2.0 DESCRIPTION OF ACTIVITIES AT USAMRIID

2.1 Introduction

In this section, the current and currently planned USAMRIID activities and the facilities in which they will be conducted are described. In addition, the policies, procedures, and operational and engineering features designed to mitigate (lessen or eliminate) potential environmental impacts of these USAMRIID activities are described.

2.2 Organization, Location, and Facilities

The mission of USAMRIID is to conduct research to develop strategies, products, information, procedures, and training for medical defense against validated biological warfare agents and naturally occurring agents of military relevance that require special containment (USAMRIID, 2000a).

USAMRIID facilities consist of a total of 355,358 square feet (USAMRIID, 2000b). USAMRIID is located in Buildings 1425 and 1412, and part of Building 1301 on Area A of Fort Detrick in Frederick, Maryland (see Figure 2-1). Building 1425 contains 249,059 square feet of space for laboratories, hazardous materials storage, general storage, and administration. Laboratory space totals 228,874 square feet. Building 1425 was constructed in two phases, in 1970 and 1972. A recent addition contains additional storage space. USAMRIID occupies the 4,834 square feet of space that formerly housed the Health Clinic. Building 1412, which is used for aerosol challenges, was constructed in 1958 and has 73,920 square feet of laboratory space and a nonhuman primate housing facility and cagewash facilities (USAMRIID, 2000f). USAMRIID also occupies 6,734 square feet of laboratory space in the 47,801 square-foot U.S. Department of Agriculture (USDA) building (Building 1301) (Federline, 2000). USAMRIID activities conducted in laboratories require various BSLs (see Section 2.4.2). USAMRIID has a total of 55,148 square feet of BSL-3 (48,683 square feet) and BSL-4 (6,465 square feet) space (USAMRIID, 2000a).

The USAMRIID animal farm is located on Area B west of Area A in Frederick (see Figure 2-2). The Large Animal Research Facility (LARF) consists of 120 acres, including 108 acres of pasture. Four buildings comprise the USAMRIID facilities at this location. Building 1221, a research barn, is 2,792 square feet. Building 1259, the administrative area, is 12,139 square feet. Building 1258 (3,301 square feet) and Building 1261 (2,880 square feet) are storage facilities for cages, hay, and farm equipment. The 520th Theater Army Medical Laboratory occupies several other buildings at the USAMRIID animal farm (Federline, 2000; USAMRIID, 2000b). The LARF also uses Building 1656, a dairy barn on Area A, for storage of hay and animal cages (USAMRIID, 2000f).

Fort Detrick is located in the northwest corner of Frederick (see Figure 2-3). Area A covers approximately 805 acres on Fort Detrick, and Area B covers approximately 400 acres. Additional information about Fort Detrick may be obtained from the EPG (USAG, 1998).

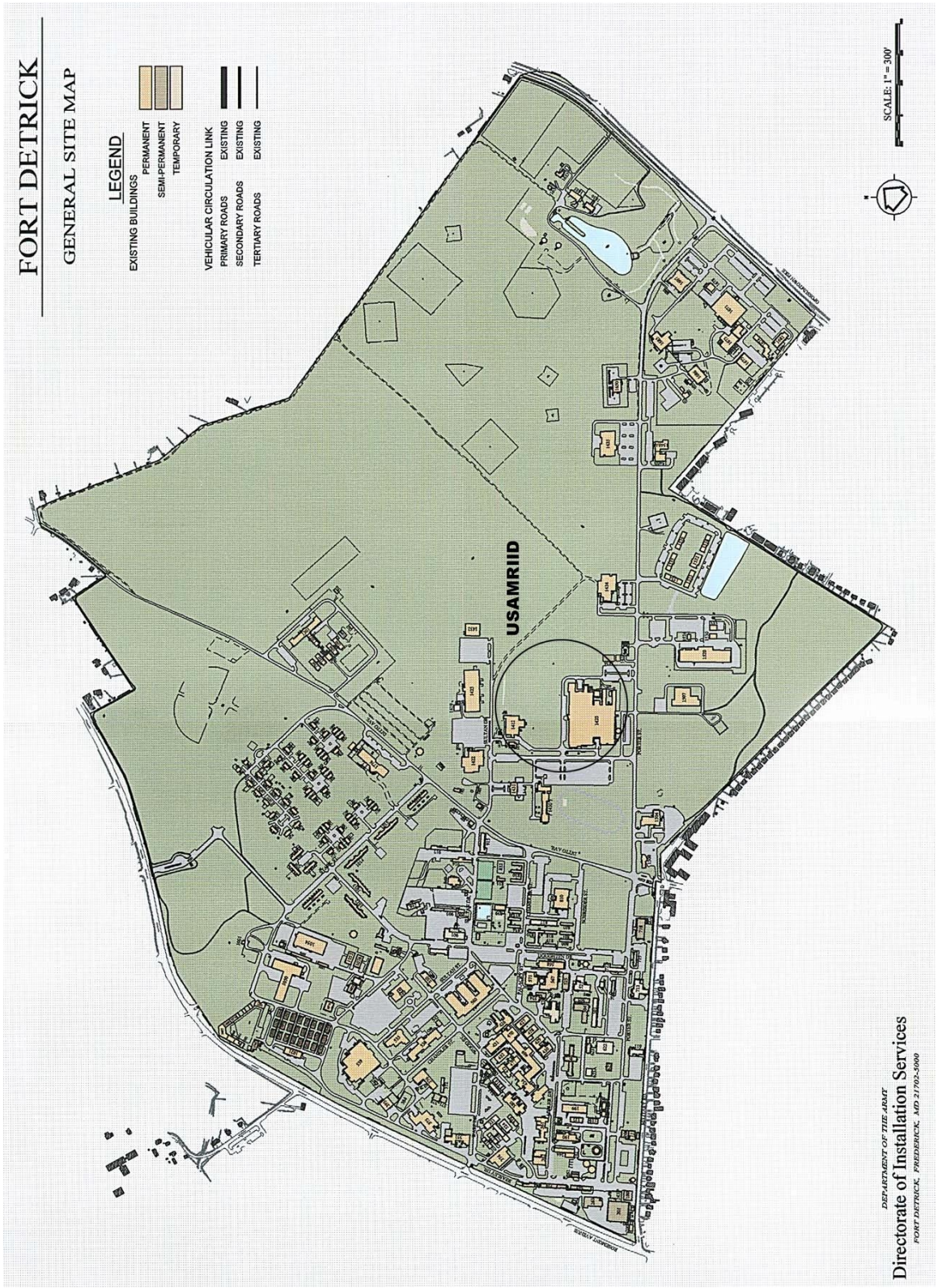

Figure 2-1. Location of USAMRIID on Area A at Fort Detrick

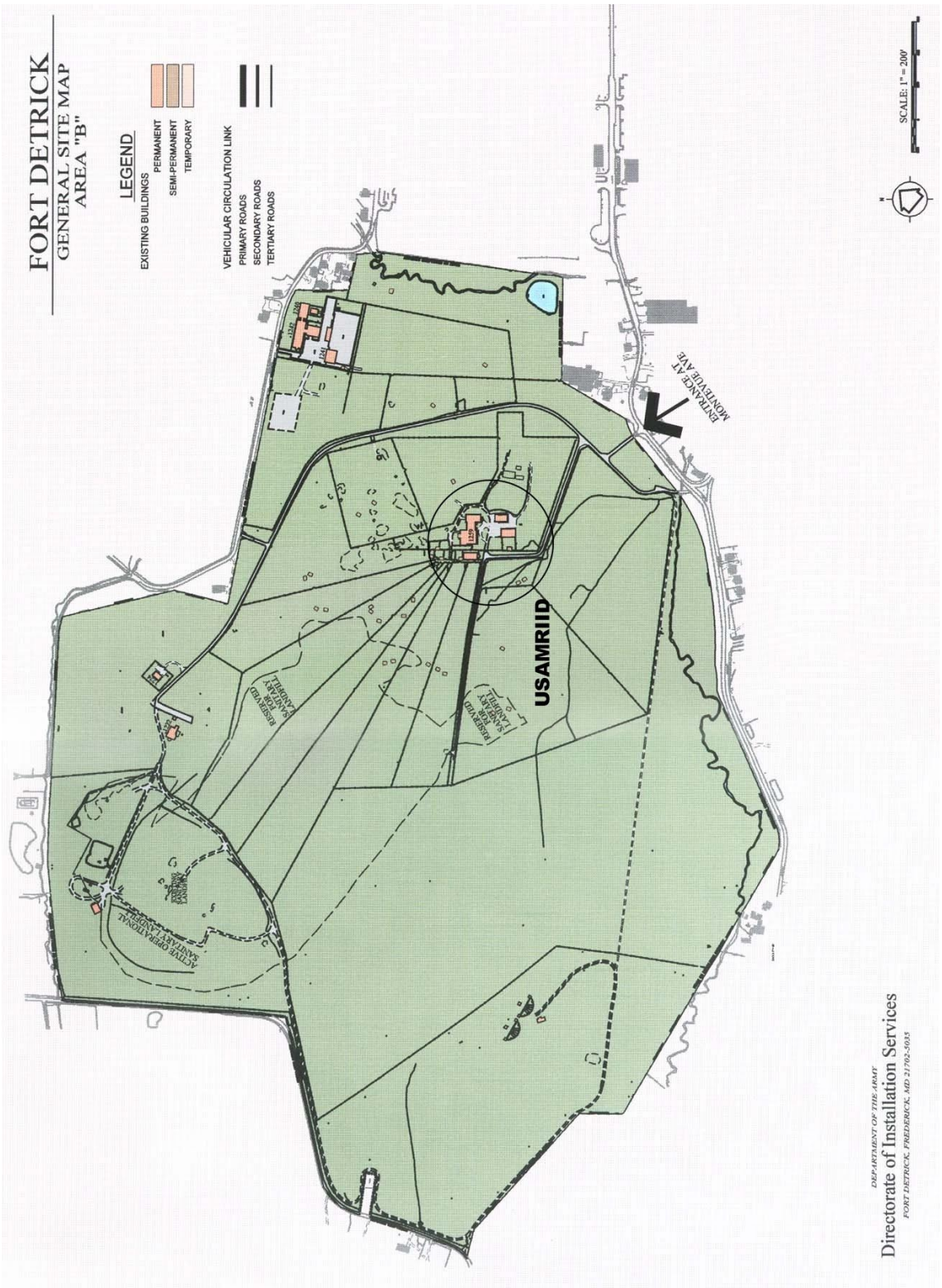

Figure 2-2. Location of USAMRIID on Area B at Fort Detrick

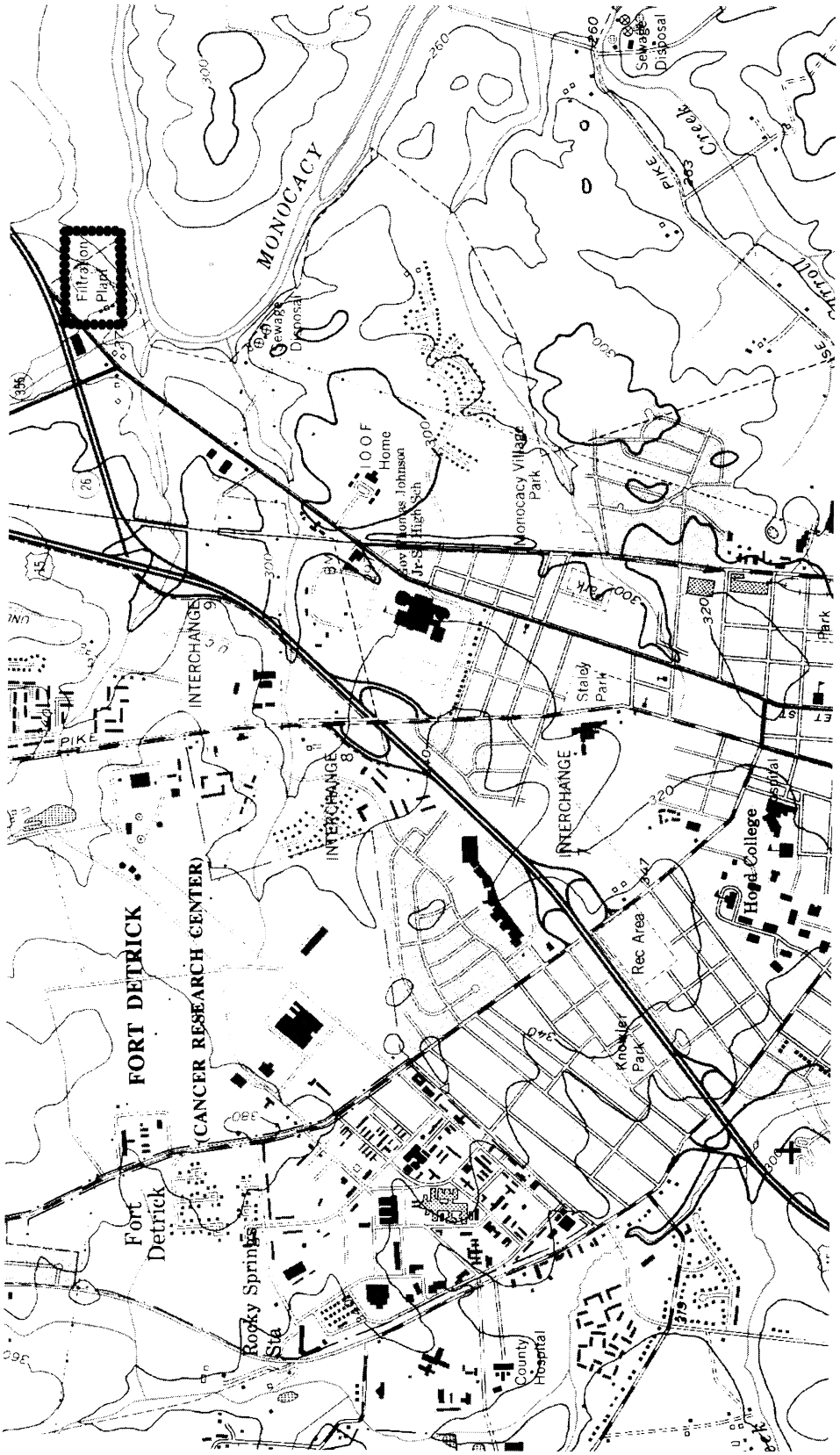

Figure 2-3. Location of Fort Detrick in Frederick, Maryland

2.3 Activities

USAMRIID conducts research to develop strategies, products, information, procedures, and training programs for medical defense against biological warfare threats and infectious diseases. Studies on the pathogenesis, diagnosis, prophylaxis, treatment, and epidemiology of infectious diseases and toxins are conducted. In many cases, the disease-causing organisms (bacteria, viruses, and rickettsia) require biological containment facilities to ensure the safety of the laboratory workers and the environment. A large variety of viral and bacterial agents are grown to support the research activities.

Medical products developed include drugs and vaccines. Vaccine development can include changing the disease-causing properties by attenuation or reduction of virulence or toxicity and efforts to enhance immunogenicity. Genetic engineering (recombinant deoxyribonucleic acid [DNA]) technologies, as well as other common tools of molecular biology, are used to conduct research on new approaches to vaccine design. Activities also include the development of diagnostic capabilities, and various medical management procedures, as well as production of critical reagents, such as proteins and antibodies, for use in development of diagnostic tests. Laboratory animals are exposed to aerosols of biological agents during efficacy testing of vaccine candidates or therapeutic agents against those validated biological threats. Aerosols are generated within enclosed Class III biological safety cabinets (BSC) for use in basic aerobiological research.

Current studies include work on improved vaccines for anthrax, Venezuelan equine encephalitis, plague, and botulism, and on new vaccines for toxins such as staphylococcal enterotoxins and ricin toxin. Research on medical countermeasures for viral hemorrhagic fevers and arboviral illnesses is being conducted. Laboratory and field diagnostic assays for agents considered to be biological warfare or endemic disease threats are also being developed. Etiologic agents are used in research and laboratory work involving development of vaccines, diagnostic assays and reagents, and antiviral compounds, and for validation of Good Laboratory Practices (GLP) procedures and data. The USAMRIID Safety and Radiation Protection Office maintains a registry of bacterial, viral, fungal, and toxin agents in use at the facility. Bacteria used in research and categorized as BSL-1, BSL-2, or BSL-3 include, for example, *Burkholderia mallei, Burkholderia pseudomallei, Francisella tularensis, Staphylococcus aureus*, *Salmonella species*, *Clostridium botulinum*, *Bacillus species*, and *Yersinia pestis*. Viruses requiring BSL-1, BSL-2, BSL-3, or BSL-4 and used in research and development activities consist of Yellow Fever virus, Hantaan virus, Venezuelan equine encephalitis virus, Lassa Fever virus, Marburg virus, and Ebola virus. *Candida albicans*, a BSL-2 fungus, is used in quality control studies in diagnostic assay development. Toxins used in vaccine and diagnostic assay development include the following bacterial toxins: botulinum toxin (*Clostridium botulinum*), cholera toxin (*Vibrio cholerae*), and enterotoxins (*Staphylococcus aureus*). Other toxins used include saxitoxin and ciguatoxin (from marine organisms), ricin from the castor bean, snake and fish toxins, and T-2 mycotoxins (from fungi) (USAMRIID, 2000f).

2.4 Safety Policies and Procedures

The following section describes the safety policies and procedures under which the current and currently planned USAMRIID activities must be conducted. The incorporation of accepted safety practices and procedures in implementing these activities ensures environmental integrity and the health and safety of workers and the public as required by Federal, DoD, DA, state, and local laws, regulations, and policies.

2.4.1 General Safety Requirements

USAMRIID must adhere to DoD, DA, Federal, state, and local laws and regulations pertaining to occupational health, safety, and the environment including the safe use, handling, and disposal of etiologic agents and other potentially hazardous materials such as chemicals. All activities of a potentially hazardous nature performed by either civilian or military personnel at DA work sites (including contractor sites) are governed by *The Army Safety Program* (AR 385-10) that implements, by reference, all applicable Federal, state, local, DoD, and DA requirements. This comprehensive safety regulation defines safety management and responsibility, personnel training, personal protective equipment (PPE) and clothing, waste-handling procedures, inspections, spill and emergency procedures, hazard communication, and other elements essential to safety.

The USAMRIID Safety and Radiation Protection Office (SRPO) is responsible for the Safety Program, including preparation of regulations and initial training in biological containment laboratory operations and hazard communication. USAMRIID's Facility Safety Plan (FSP), the *Safety Program Manual*, details the significant potential hazards associated with operations as well as the mitigation measures employed to ensure safe operation. The *Safety Program Manual* consists of USAMRIID regulations pertinent to safety. A list of these regulations is provided in Appendix A. The proponent of these regulations includes the divisions of Safety and Radiation Protection, Logistics, and Veterinary Medicine. The manual also contains lists of documents pertinent to safety from the USAMRMC, USAG, and each USAMRIID division. The *Safety Program Manual* includes the *Safety Office Instructional Materials* and *Safety Glossary* (USAMRIID, 2000f). Some USAMRIID regulations detail facility engineering and work practice controls, emergency preparedness, training, standard operating procedures (SOPs), and other safety guidelines and requirements. USAMRIID Regulation 385-14, *Safety Program*, dated 3 June 1991, describes the policy, responsibilities, and procedures of the facility safety program. SOPs, prepared by the USAMRIID SRPO, contain instructions for accomplishing a given task in a safe and consistent manner. SOPs are developed, approved, and implemented in accordance with USAMRIID Regulation 385-14.

2.4.2 Biological Safety

USAMRIID activities require the use of etiologic agents. Guidelines established by the Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) and published in *Biosafety in Microbiological and Biomedical Laboratories* (CDC/NIH, 1999) describe the laboratory practices, techniques, facilities, and equipment recommended to contain

etiologic agents of varying degrees of pathogenicity and virulence. These measures have been developed to minimize risks to human health (workers and the community) and the environment. The DA has established regulations that mandate adherence to these guidelines. Thus work sponsored by the DA and involving the use of etiologic agents, such as those likely to be used during the course of proposed activities, must be conducted in accordance with these guidelines and must also meet the safety requirements detailed in AR 385-69 (32 CFR 626, *Department of the Army, Biological Defense Safety Program*) and DA Pamphlet 385-69 (32 CFR 627, *Department of the Army, The Biological Defense Safety Program, Technical Safety Requirements)*.

USAMRIID Regulation 385-3, *Microbiological Safety*, dated 1 November 1990, establishes the policy and responsibility for the facility's microbiological safety program. Committees that assess and review issues associated with biological safety (Institutional Biosafety Committee [IBC]) and the care and use of animals (Laboratory Animal Care and Use Committee [LACUC]) exist at USAMRIID. In accordance with USAMRIID Regulation 385-4, *Institutional Biosafety Committee*, dated 1 November 1990, the IBC considers all research involving, but not limited to, recombinant DNA molecules (USAMRIID, 2000d).

2.4.2.1 Biosafety Levels

The CDC/NIH guidelines describe the four BSLs established for conducting laboratory operations with etiologic agents and/or their toxins. The guidelines also describe four animal BSLs (ABSLs) for operations involving the use of animals infected or potentially infected with etiologic agents requiring BSL-1 through BSL-4 containment. BSL-1 practices, safety equipment, and facilities are appropriate for facilities in which work involves defined and characterized strains of viable microorganisms not known to cause disease in healthy adult humans. BSL-2 practices, safety equipment, and facilities are appropriate for facilities in which work involves the broad spectrum of indigenous (native) moderate-risk etiologic agents present in the community and associated with human disease of varying severity. Work with indigenous or exotic etiologic agents with potential for aerosol transmission and that may have serious or lethal consequences requires BSL-3 containment. BSL-3 "differs from BSL-2 in that (1) more extensive training in handling pathogenic and potentially lethal agents is necessary for laboratory personnel; (2) all procedures involving the manipulation of infectious material are conducted within biological safety cabinets, other physical containment devices, or by personnel wearing appropriate personal protective clothing devices; [and] (3) the laboratory has special engineering and design features, including access zones, sealed penetrations, and directional airflow." BSL-4 practices, safety equipment, and facilities are required for work with dangerous and exotic etiologic agents posing a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease (DA Pamphlet 385-69). ABSL-1 through ABSL-4 practices, equipment, and facilities also provide increasing levels of containment. The CDC/NIH guidelines include "agent summary statements" that provide information on laboratory hazards associated with specific agents and guidance for selecting the appropriate level of containment. Under the CDC/NIH guidelines, the laboratory director is responsible for determining the appropriate BSL based upon "the virulence, pathogenicity, biological stability, route of spread, and communicability of the agent; the nature or function of the laboratory; the procedures and manipulations involving the agent; the endemicity of the agent; and the availability of effective vaccines or therapeutic measures" (CDC/NIH, 1999).

USAMRIID activities require the use of up to BSL-4 work practices and engineering controls because the activities require the use of etiologic agents. BSL-2 activities are conducted in accordance with USAMRIID Regulation 385-9, *Biosafety Level 2 Operations*, dated 1 December 1990. BSL-3 and BSL-4 biological containment operations and activities are conducted in accordance with USAMRIID Regulation 385-69, *Biocontainment Laboratory Operation (Biosafety Levels 3 and 4)*, dated 1 March 1995. All BSL-3 and BSL-4 facilities at USAMRIID meet or exceed criteria set forth in the CDC/NIH guidelines (CDC/NIH, 1999). USAMRIID conducts these activities in 48,683-square feet of BSL-3 containment laboratories and 6,465 square feet of BSL-4 containment laboratories (USAMRIID, 2000a).

In accordance with DA Pamphlet 385-69 and USAMRIID Regulation 385-69, access to BSL-3/ABSL-3 and BSL-4/ABSL-4 facilities are restricted to personnel directly involved with the work. Individuals determined during medical baseline evaluation to be at increased risk of acquiring infections or for whom infection would be unusually hazardous are not permitted to enter. Authorized personnel must be informed of the potential hazards associated with entry and the safeguards necessary for their safety. Biological containment areas must have signs posted on entry doors indicating their BSL-3/ABSL-3 or BSL-4/ABSL-4 designation, agent(s) in use, and individuals to contact in case of an emergency. At USAMRIID, the required information is posted outside the anteroom of each biological containment suite. BSL-3/ABSL-3 and BSL-4/ABSL-4 suites are locked at all times. Two sets of doors must be entered to access biological containment areas. An electronic key card system restricts access to the laboratories from access corridors or other laboratories to authorized personnel. A clearly demarcated zone separates the laboratory areas from non-laboratory areas. Prior to entering BSL-3/ABSL-3 and BSL-4/ABSL-4 suites, personnel must change into long-sleeved laboratory clothing and pass through a room-sized airlock. Personnel place their laboratory clothing in a laundry container, shower, and change into street clothes in the anteroom prior to exiting the suites. Upon exiting biological containment areas, personnel must wash their hair or wear a cap. Shoes worn in these areas are left in the change room (USAMRIID, 2000a).

PPE includes gloves, respirators, goggles, face shields, and hearing protection as needed. In BSL-1 and BSL-2 areas, workers must wear a fully fastened laboratory coat. As previously noted, personnel must wear special laboratory clothing in BSL-3/ABSL-3 and BSL-4/ABSL-4 areas. BSL-4/ABSL-4 biological containment differs from BSL-3/ABSL-3 in that each BSL-4/ABSL-4 worker wears a one-piece positive pressure protective suit ventilated by its own air supply system. Workers are required to decontaminate the surface of their suits in a chemical disinfectant shower prior to leaving the area (USAMRIID, 2000a).

Germicides are used to disinfect BSCs, room surfaces, exterior surfaces of certain items prior to their removal from BSL-3/ABSL-3 and BSL-4/ABSL-4 suites, and in showers used by personnel wearing positive pressure protective suits. Potentially contaminated work materials must not be removed from BSL-3/ABSL-3 and BSL-4/ABSL-4 suites until they are rendered innocuous by chemical disinfection or autoclaving. Two steam autoclaves are available in each biological containment suite enabling items to be sterilized. A pass-through autoclave is provided for decontamination of materials passing out of the laboratory. The autoclave door that opens to the corridor outside of the biological containment suite is sealed to the outer wall and automatically controlled so that it may only be opened after the autoclave sterilization cycle is complete. A pass-through surface decontamination system, fumigation chamber, and ultraviolet light

treatment chamber are available for decontaminating materials that cannot be autoclaved. In addition, the airlock may be sealed and used to decontaminate large items prior to removal from a BSL-3/ABSL-3 or BSL-4/ABSL-4 suite. All BSL-4/ABSL-4 waste is autoclaved twice prior to removal from the suites. Items which may not be autoclaved are decontaminated using paraformaldehyde, or in rare cases, ethylene oxide (USAMRIID, 2000a). USAMRIID Regulation 385-2, *Decontamination of Equipment and Materials Using Paraformaldehyde*, dated 19 June 1998, and USAMRIID Regulation 385-17, *Decontamination of Containment Areas with Paraformaldehyde*, dated 19 February 1999, detail decontamination procedures requiring paraformaldehyde. In addition, USAMRIID Regulation 385-69, *Biocontainment Laboratory Operations (Biosafety Levels 3 & 4)*, dated 1 March 1995, contains procedures for sterilizing using ethylene oxide. The *Safety Program Manual* contains USAMRIID regulations that detail the permitted flow of people, equipment, animals, and experimental materials. Restrictions on the movement of these entities are designed to prevent cross-contamination of adjacent areas and a breach in containment, and to protect worker health and safety.

2.4.2.2 Special Engineering Features

Special engineering features that control airflow are required to achieve BSL-3/ABSL-3 and BSL-4/ABSL-4 containment. In Building 1425, each BSL-3/ABSL-3 and BSL-4/ABSL-4 laboratory is an airtight suite with its own air exhaust system while Building 1412 may be considered one large suite. There are back-up exhaust fans for each air-handling system. Each biological containment suite is composed of several rooms, each with its own temperature control. BSL-3/ABSL-3 and BSL-4/ABSL-4 laboratories are maintained under negative pressure to surrounding hallways, resulting in a net flow of air into each suite. In addition, there is an increasingly negative air pressure differential maintained within each suite as follows: change rooms and entry airlock, conference room and office, central hallway, and research laboratories and animal rooms. The office space is maintained under positive pressure to the hallway. The research laboratories and animal rooms have the most negative air pressure. Each air supply system includes alarms, back-up supply compressors, emergency breathing air tanks, and a high efficiency particulate air (HEPA) filter. (A HEPA filter will remove 99.97% of particles of 0.3 micrometers, which are the most difficult to trap.) BSL-4/ABSL-4 suites are entered via airlocks with airtight doors (USAMRIID, 2000a).

Double door airlocks ensure that only one door can be opened at any time, maintaining the negative pressure in the BSL-3/ABSL-3 or BSL-4/ABSL-4 areas. Doors are equipped with electronically controlled magnetic locks. Magnehelic gauges are mounted adjacent to the door of each biological containment laboratory and equipment room and above the emergency exit door of each suite to indicate the negative pressure differential. The BSL-4/ABSL-4 areas have a duplicate filtration unit and exhaust fan, and an emergency power source is activated automatically in the event that the primary power source is interrupted. Emergency lighting and alarm systems are provided. Each room in the biological containment areas has a ceiling-mounted heat detector. Buildings 1412 and 1425 have visible and audible fire notification systems (USAMRIID, 2000a, 2000d).

BSL-3/ABSL-3 and BSL-4/ABSL-4 suites contain dedicated air supply and exhaust systems. The emergency air supply for positive pressure suites (i.e., bottled compressed air) serves as a back-up system. The ventilation systems are designed for one pass air. Exhaust air from each

suite is passed through a HEPA filter (two HEPA filters in series if the air is from BSL-4), is not recirculated to any other area of the building, and is vented to the outside of the building (USAMRIID, 2001). The exhaust air is dispersed away from high traffic areas and fresh air intakes (USAMRIID, 2000a). Exhaust air stacks are located a minimum of 50 feet from fresh air intakes (USAMRIID, 2000d).

The walls, floors, and ceilings of BSL-3/ABSL-3 and BSL-4/ABSL-4 rooms form a sealed internal shell that is pest-proof and facilitates cleaning and decontamination. Wall penetrations also are sealed, and walls and floors are painted with epoxy. Floor drains are filled with disinfectants or solutions appropriate for decontaminating the etiologic agent being studied in the laboratory. These drains are connected to the liquid waste decontamination/holding tank system. Sewer line vents are protected with HEPA filters. Liquid wastes from laboratory sinks, BSCs, floors, autoclaves, showers, and toilets enter Fort Detrick's dedicated Laboratory Sewer System (LSS) and are decontaminated centrally. The central vacuum system is dedicated to the BSL-3/ABSL-3 and BSL-4/ABSL-4 laboratories. At each service cock, the system contains in-line HEPA filters designed for in-place decontamination and replacement. Liquid and gas services are protected with traps and/or filters to prevent backflow contamination (USAMRIID, 2000a).

Class II Type A BSCs are located in individual BSL-3/ABSL-3 and BSL-4/ABSL-4 laboratories. Some BSL-4 suites are configured with Class III BSCs, which provide space in which etiologic agents and laboratory animals can be safely manipulated without introducing an etiologic agent into the laboratory air. The air leaving Class III BSCs passes through a HEPA filter upon exiting the cabinet before discharge directly into the laboratory exhaust system. BSCs are maintained under negative pressure and undergo semiannual or annual certifications for performance in accordance with USAMRIID Regulation 385-7, *Biological Safety Cabinet and Chemical Fume Hood Monitoring and Certification Program*, dated 3 February 1997, and USAMRIID Regulation 385-68, *Class III Biological Safety Cabinet and Glove Box Monitoring and Field Certification Program*, dated 15 April 1998 (USAMRIID, 2000a).

USAMRIID's *Safety Program Manual* contains regulations for laboratory safety procedures, first aid, fire fighting, inspections, decontamination, access, and emergency preparedness. Regulations detailing work in BSL-2, BSL-3, and BSL-4 areas are included in the FSP. Personnel must acknowledge in writing that they have read and understood the contents of USAMRIID Regulation 385-69, *Biocontainment Laboratory Operations (Biosafety Levels 3 & 4)*.

The Commander, USAMRIID and the SRPO must approve all requests from investigators to study etiologic agents. The SRPO maintains a registry of agents to insure that the area where the proposed work will be conducted meets the biological containment level required for the etiologic agent. USAMRIID Headquarters and each Division Chief receive copies of the agent registry on a quarterly basis for verification. Etiologic agents are stored in secured refrigerators or freezers in laboratories or suites where access is restricted to authorized personnel. When work with etiologic agents is completed, they are disposed of by autoclave or appropriate chemical decontamination, or are stored or archived in a secured refrigerator or freezer (USAMRIID, 2000a).

The mission of USAMRIID's Department of Aerobiology and Product Evaluation is to conduct and support research on the pathogenesis, prophylaxis, and therapy of disease or intoxication caused by exposure through the respiratory tract to aerosolized biological warfare agents. As part of this mission, aerosols are generated for basic aerobiological research and applied research. Testing the efficacy of vaccine and therapeutic agents requires exposure of laboratory animals via aerosol challenge. Such testing is conducted in accordance with DoD, DA, and USAMRIID regulations. Typically, a vacuum and air pressure-driven unilaminar, dynamic flow system is used in a (gas-tight) Class III BSC. The etiologic agent undergoing testing is suspended in liquid that is placed in a nebulizer jar. Pressurized air supplied to the nebulizer forces the etiologic agent suspension out of several orifices, creating aerosolized particles. After leaving the nebulizer, the flow of aerosol is mixed with air in a stainless steel mixing tube. The combined airflow and aerosol are sufficient to expose a small animal in an exposure chamber to the aerosol. All workers who remove animals and decontaminate or remove items from a Class III BSC wear PPE that protects them from exposure to the etiologic agent (USAMRIID, 2000a).

2.4.3 Transportation of Etiologic Agents and Registration of Facilities

Packaging and shipment or transport of etiologic agents are conducted in accordance with AR 385-69 and USAMRIID Regulation 385-13, *Shipment of Materials*, dated 3 April 2000. USAMRIID laboratory personnel package etiologic agents in appropriate primary and secondary containers. Personnel in the Material Control Branch, Logistics Division complete the packaging process. The packaged etiologic agents are transported to the USAG Transportation Office for chain-of-custody transport via commercial carrier (USAMRIID, 2000a).

Facilities that transfer or receive certain etiologic agents are required to apply for registration with the CDC in accordance with 42 CFR 72.6, *Additional Requirements for Facilities Transferring or Receiving Select Agents*. USAMRIID has met CDC requirements and is registered (CDC Select Agent Permit Number 19970516-348). This registration was updated on 12 February 1999 (USAMRIID, 2000a). The transfer of agents to and from USAMRIID is documented and reported to the CDC.

The USDA has issued permits to USAMRIID to transport and use restricted pathogens. Such permits allow USAMRIID to import serum and tissue specimens from domestic and wild animals (USAMRIID, 2000d). USDA permit restrictions are based on the animal-derived material being imported (USAMRIID, 2000f).

2.4.4 Inspections and Documentation

Biological defense work involving the use of etiologic agents must follow the record-keeping provisions detailed in AR 385-69 (32 CFR 626, *Department of the Army, Biological Defense Safety Program*) and DA Pamphlet 385-69 (32 CFR 627, *Department of the Army, The Biological Defense Safety Program, Technical Safety Requirements)*. In accordance with DA Pamphlet 385-69, records that detail the following must be maintained for 3 years: safety audits and corrective measures; SOP reviews; risk assessments of new procedures; training records; testing and certification records for laboratory safety equipment; safety committee meeting minutes; and comments made by outside auditors or inspectors.

Safety inspections are an integral part of USAMRIID operations. AR 385-69 requires monthly inspection of BSL-3/ABSL-3 and BSL-4/ABSL-4 facilities, and supervisors are required to conduct weekly inspections of their work areas. Division Safety Representatives conduct monthly inspections and send the reports to the SRPO. SRPO personnel conduct quarterly biosafety inspections of BSL-2, BSL-3, and BSL-4 suites and annual inspections of administrative areas (USAMRIID, 2000a).

Inspections of the USAMRIID BSL-1, BSL-2, BSL-3, and BSL-4 laboratories are conducted in accordance with AR 385-69 and USAMRIID Regulation 385-69 (*Biocontainment Laboratory Operations (Biosafety Levels 3 and 4))*. The BSL-1, BSL-2, BSL-3, and BSL-4 laboratories, animal facilities, and support facilities are inspected using the Basic Checklist for Biosafety Levels 1, 2, and 3 (DA Pamphlet 385-69, 32 CFR 627, *Appendix C - Laboratory Safety Inspection Checklist*). The animal containment facilities meet physical standards for ABSL-3 and ABSL-4 as described in the CDC/NIH guidelines and DA Pamphlet 385-69. The BSL-1, BSL-2, BSL-3, and BSL-4 laboratories, related equipment, policies, and procedures also meet the biosafety standards described in the CDC/NIH guidelines (Hawley, 2000a).

2.4.5 Chemical Safety

USAMRIID Regulation 385-29, *Hazard Communication Program*, dated 29 December 1999, and USAMRIID Regulation 385-30, *Chemical Hygiene Plan*, dated 29 November 1999 are part of the *Safety Program Manual*. The Hazard Communication Program meets the requirements of 29 CFR 1910.1200, *Hazard Communication*, and applies to all personnel who work with or may be exposed to hazardous chemicals under normal conditions of use, other than "laboratory use" as defined in the Occupational Safety and Health Administration's (OSHA) *Occupational Exposure to Hazardous Chemicals in Laboratories* (29 CFR 1910.1450) or in a foreseeable emergency. USAMRIID Regulation 385-30 establishes policies and procedures for the handling of hazardous chemicals in accordance with 29 CFR 1910.1450. *Occupational Exposure to Hazardous Chemicals in Laboratories* describes the safety standards that must be applied in a laboratory setting in which chemical hazards exist. Medical monitoring, preparation of written training and operational protocols, use of Material Safety Data Sheets (MSDSs) and labels, and the certification of safety apparatus may be required. In addition, 29 CFR 1910.1450 describes plan implementation and managerial responsibilities. Detailed, written instructions (SOPs) for the safe use, handling, and disposal of hazardous material must be available in work areas. The Chemical Hygiene Officer maintains a chemical inventory. OSHA regulations require training for all personnel prior to work assignments or new tasks with the potential for exposure to hazardous chemicals. Training includes instructions for accessing MSDSs. A chemical hygiene plan (CHP) and laboratory-specific procedures must provide information about handling controlled substances, chemical acquisition, chemical storage, potential health risks, environmental monitoring, PPE, use of fume hoods, safety procedures, inspections, and laboratory audits. In accordance with these regulations, written safety policies and procedures must be available for all laboratory personnel. At USAMRIID, training is ongoing based on new exposures or procedure changes. For information about chemical waste handling and disposal, see Section 2.6.

USAMRIID activities require the use of certain chemicals (USAMRIID, 2000a). USAMRIID policies and procedures for the safe handling and use of chemicals are contained in a CHP as required by OSHA regulations.

2.4.6 Radiologic Safety

USAMRIID has two valid U.S. Nuclear Regulatory Commission (NRC) licenses. NRC License Number 19-11831-01 (by-product material) is for two gamma cell irradiators and NRC License Number 19-11831-03 (Type B broad license) permits USAMRIID to use radioisotopes and Nickel (Ni)–63 source(s). The quantities of radiological waste generated by USAMRIID and other Fort Detrick activities (i.e., Frederick Cancer Research and Development Center and USDA) are provided in Table 2-1. Fort Detrick Regulation 385-3, *Radioactive Waste*, dated 11 June 1997 describes procedures for safe handling of radioactive materials and wastes (USAG, 1997a). Details of these procedures are provided in the EPG (USAG, 1998).

Radiological waste generated by USAMRIID activities is packaged in accordance with Fort Detrick Regulation 385-3. The radiological waste is transported to the Directorate of Installation Services' (DIS) Radioactive Waste Storage Facility (Building 261 in Area A). Disposal of all radiological waste is coordinated with the Radiation Waste Manager in accordance with the Fort Detrick Garrison Radioactive Material Authorizations and applicable regulations. All radiological waste is transported off the installation by commercial carrier and ultimately incinerated at the contractor's facility (see Table 2-1). The Operational Services Command (OSC) acts as the contract manager between USAMRIID and OSC-approved disposal facilities. All material is packaged in accordance with NRC, DA, U.S. Department of Transportation, OSC, Federal, state, and disposal facility requirements.

Table 2-1. Annualized Summary of Waste Streams from USAMRIID
(USAMRIID, 2000a, 2000b, 2000c, 2000d, 2000f)

Waste Type	Total Annual Quantity for USAMRIID	Total Annual Quantity for Fort Detrick	Disposal Method/ Provider
General solid waste (pounds)	322,718	3,700,758	Incinerator/Fort Detrick landfill Fort Detrick Solid Waste Management Section
Regulated medical waste (pounds)	8,742	1,282,378	Special Medical Waste Incinerator/Fort Detrick landfill Fort Detrick Solid Waste Management Section
Hazardous chemical waste (pounds)	10,385	28,421	Through Defense Reutilization Marketing Office (DRMO)
Radiologic waste (mCi)			
C-14	0	4.975	
Cr-51	0.7	43.751	
H-3	47.57	490.167	
I-125	0.101	2.234	Transfer to Fort Detrick Radiation Protection Officer (RPO) Transport by commercial carrier (GTS Duratek, Oak Ridge, TN) for disposal in incinerator
In-111	0	2.126	
Na-22	0	0.048	
P-32	15.31	266.394	
P-33	0	3.548	
S-35	217.09	274.889	
Uranyl acetate	1.76	162 (grams)	
Instruments & Articles			
H-3	0	23,230	
Am-241	0	0.047	
Wastewater – sanitary (gallons)	43,820,000	347,190,000	Fort Detrick Wastewater Treatment Plant (WWTP)
Wastewater - contaminated (gallons)	24,802,000	25,073,000	LSS - Fort Detrick Steam Sterilization Plant (SSP)

2.5 Security

USAMRIID is secured at all times and entry is controlled by an electronic access system and magnetic locking system. Exterior and interior closed circuit television cameras are used to monitor physical security. Parking is controlled and there is a safezone around the facilities. Security staff control visitors' access to USAMRIID. Access into the biological containment areas is restricted by a badge system using proximity readers as well as electronic keypads that require a personal identification number. The alarms, closed circuit television cameras, and access systems are continuously monitored. Only authorized individuals with medical clearance, appropriate immunization administered through the Special Immunizations Program (SIP), documented training, and demonstrated need are accorded electronic access into the containment laboratories. Etiologic agents are stored in the Agent Repository, which is located in a biological containment suite (USAMRIID, 2000a). The Agent Repository entry is limited to only a few selected personnel in the institute. Entry is restricted by a keypad entry system, and the entry procedure is directly monitored electronically by the Fort Detrick Provost Marshall's Office. Voice confirmation is required through that office upon entry and exit. The password for entry is changed frequently. USAMRIID personnel undergo security background checks as necessary.

2.6 Waste Stream Management

A summary of the current and projected waste volumes for USAMRIID is provided in Table 2-1. Waste generated from USAMRIID activities will include general solid waste, regulated medical waste (i.e., sharps and animal waste) (for the purposes of this document medical waste is defined, in accordance with 49 CFR 173.134, as waste or reusable material, other than a culture or stock of an infectious substance, that contains an infectious substance and is generated in activities pertaining to the diagnosis, treatment, or immunization of humans or animals, or the production or testing of biological products), hazardous chemical waste, radiological waste, and wastewater. In accordance with CDC/NIH guidelines (CDC/NIH, 1999), all waste contaminated or potentially contaminated with infectious material must be rendered noninfectious before disposal. This decontamination is accomplished by a combination of chemical and physical (autoclave) methods.

USAMRIID activities currently generate approximately 43,820,000 gallons of wastewater annually. Sanitary wastes generated by USAMRIID are released to the sanitary sewer system and treated at the Fort Detrick Wastewater Treatment Plant (WWTP) located on Area C. In addition, USAMRIID generates 24,802,000 gallons of potentially contaminated wastewater (i.e., directly generated from laboratory activities), which is routed to the WWTP via the dedicated LSS and the Fort Detrick Steam Sterilization Plant. Fort Detrick wastewater treatment facilities provide secondary treatment to wastewater received before discharge into the Monocacy River (see Section 4.7.1). The Maryland Department of the Environment (MDE) regulates the WWTP under the National Pollutant Discharge Elimination System (NPDES) program. The Fort Detrick WWTP NPDES permit number is MD0020877, and the State Discharge Permit number is 97-DP-2527.

The overall waste operation is permitted under Refuse Disposal Permit No. 1994-WIN-0341-0. All solid waste generated at USAMRIID ultimately is disposed of at the Fort Detrick Landfill by the Fort Detrick Solid Waste Management Section, either in its original form or as ash resulting from incineration. The Fort Detrick Solid Waste Management Section handles incineration of wastes at the Incinerator Complex, Building 393, on Area A.

Medical waste, predominantly consisting of sharps and animal waste, is also generated at USAMRIID. It is estimated that USAMRIID currently generates 8,742 pounds of medical waste annually. Animal bedding is treated as medical waste; however, due to the nature of the research activities conducted at the LARF, bedding and waste from that facility are not considered infectious and not disposed of as medical waste. All medical waste is bagged and subsequently incinerated in the Special Medical Waste Incinerators, which are operated under MDE Air Management Administration Temporary Permit(s) to Operate No. 10-000131-2-0066 and No. 10-000131-2-0067. Fort Detrick submitted an application for a Final Permit to Operate in March 1997, and awaits a response from the MDE (USAMRIID, 2000a, 2000c). Details on the operation of Installation incinerators, including the Special Medical Waste Incinerators, are provided in the EPG (USAG, 1998). Ash from the incinerators is sampled and test results are submitted to MDE. A free liquids test is performed on a quarterly basis, and a Toxicity Characteristic Leaching Procedure is conducted semi-annually (USAMRIID, 2000c). Medical waste is regulated by Federal, state, and local regulations to protect transporters and the public from potential hazards associated with potential contaminants. Medical waste at Fort Detrick is

incinerated in accordance with CDC/NIH guidelines (CDC/NIH, 1999). The USAMRIID RPO oversees transportation and destruction of medical waste (USAMRIID, 2000a).

USAMRIID activities generate about 10,385 pounds of hazardous chemical wastes annually (USAMRIID, 2000a). Fort Detrick's Hazardous Waste Generator Number is MD8211620267. The installation's Hazardous Waste Generator status is operational (USAMRIID, 2000d).

Formaldehyde gas produced by heating paraformaldehyde flakes or prills effectively decontaminates laboratories, equipment, materials, and air-handling systems. The U.S. Environmental Protection Agency (USEPA) granted USAMRIID quarantine exemption, 99-DD-01 (July 6, 1999; expiration date July 6, 2002) under the provision of Section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the use of paraformaldehyde to decontaminate biological containment areas, BSCs, and HEPA filters in the ventilation systems to prevent the release of infectious microorganisms from containment areas. USAMRIID Regulation 385-17, *Decontamination of Containment Areas with Paraformaldehyde*, dated 19 February 1999, and USAMRIID Regulation 385-2, *Decontamination of Equipment and Materials Using Paraformaldehyde*, dated 19 June 1998, detail the policies, responsibilities, and procedures for decontamination. Periodically, the BSL-3/ABLS-3 and BSL-4/ABSL-4 facilities are decontaminated with paraformaldehyde. Annually, an average of 59 pounds of paraformaldehyde was used for decontamination procedures between 1997 and 1999 (USAMRIID, 2000d). Anhydrous ammonia (ammonium bicarbonate powder) is used to neutralize the formaldehyde gas produced. The quantity of anhydrous ammonia used is 10% more than the amount of paraformaldehyde required for the decontamination as established in USAMRIID Regulations 385-17 and 385-2 (USAMRIID, 2000f). Monitoring of formaldehyde levels is used to confirm that concentrations are below those considered harmful to human health prior to workers re-entering the biological containment suites.

2.7 Animal Care and Use

The care and use of laboratory animals must comply with standards specified in AR 70-18 (*The Use of Animals in DoD Programs*) and the Animal Welfare Act (9 CFR 14). Facilities working with etiologic agents in testing biological defense products (e.g., vaccines) must comply with rules promulgated under 21 USC 154. The *Guide for the Care and Use of Laboratory Animals*, U.S. Department of Health and Human Services (DHHS) Publication 86-23 (National Research Council, 1996) also sets standards for animal-handling practices and the quality of care. The Council on Accreditation of the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC International) evaluates animal facilities and animal care and use programs at USAMRIID every 3 years with annual reporting to ensure maintenance of appropriate standards. AAALAC inspected USAMRIID facilities in March 1998 (USAMRIID, 2000d). On June 28, 1998, AAALAC International continued Full Accreditation for USAMRIID animal facilities and programs (AAALAC, 1998). The AAALAC inspected USAMRIID in March 2001. USAMRIID is currently awaiting the updated full accreditation; however, it has authority to operate under the accreditation issued June 28, 1998, until the updated accreditation is issued. Guidelines and procedures for the medical and routine care and use of animals at the USAMRIID LARF are detailed in USAMRIID SOP UIR501, *Standard Operating Procedure, Large Animal Research Facility*, dated 29 March 1995.

USAMRIID's Veterinary Medicine Division (VMD) performs various professional, technical, and service functions for USAMRIID and its scientists. The primary mission of the VMD is to provide support, research, and consultation in laboratory animal medicine; attending veterinary care; comprehensive animal husbandry; training in laboratory animal medicine, science, and animal care and use procedures; and review of research protocols for proper and lawful animal use. The Division has three departments: Department of Laboratory Animal Medicine, Department of Animal Husbandry, and the Department of Applied Research Support. The Division Chief, a veterinarian who is board-certified in Laboratory Animal Medicine, acts as the principal advisor to the Commander, USAMRIID, on animal care and use laws and welfare. In addition, the Division Chief serves as Chairman of the LACUC, and is the Preceptor for Army Veterinary Corps officers-in-training in the DA's postdoctoral training program in Laboratory Animal Medicine. The VMD includes an administrative specialist primarily dedicated to LACUC operations, a Division secretary, 9 Army Veterinary Corps officers, and 20 enlisted animal care technicians (USAMRIID, 2000a).

Some USAMRIID activities require the use of laboratory animals. The total number of laboratory animals required depends on test requirements. All studies are designed to minimize the use of laboratory animals. In fiscal year (FY) 1999, USAMRIID's animal population was 51,377. It is expected that USAMRIID will require 56,515 animals in FY 2000, a 10% increase.

The LACUC oversees all aspects of the animal facilities and program at USAMRIID including research involving animals, research protocol reviews, documentation of training reviews, and biannual facility inspections. Animals are housed in some form of animal caging containment (e.g., cage tops with filters; and laminar flow enclosures). All studies must be conducted in Class II or Class III BSCs. Animals are held in cages within Class III BSCs or in partial containment cages. The Small Animal Section at USAMRIID has a revolving monthly census of approximately 6,000 animals. In order of descending quantity, the small animal species include mice, hamsters, guinea pigs, rabbits, chinchillas, and rats. Strain 13 guinea pigs are bred at USAMRIID while all other small animals are obtained from commercial vendors. Some large animals are not housed at the LARF. USAMRIID maintains a nonhuman primate colony with a varying census. Of the current census of 419 nonhuman primates, 212 are involved in research protocols. Of the remaining 207 nonhuman primates housed at the facility, 88 will likely be assigned to animal protocol research after release from their current quarantine status. USAMRIID SOPs specifying animal care include: environmental conditions; sanitation; acquisition, quarantine, and distribution of animals; randomization and identification of animals; animal handling including sentinel and quality control; animal status and diagnostics; food and fluids; administration of test materials; anesthesia, treatment, and euthanasia; and sample collection (USAMRIID, 2000a, 2000g; Hawley, 2000b).

The LARF animal census consists of 10 horses (6 for development of test reagents and 4 retired caisson horses), 17 goats, 32 sheep, and 15 geese. Animals currently used for research in accordance with the VMD Quality Assurance Protocol include 2 of the horses, all of the sheep and geese, and 7 of the goats (USAMRIID, 2000b).

2.8 Human Health and Safety

2.8.1 Occupational Health and Safety

Protective measures to ensure worker health and safety include training, education, vaccination (immunization), and the medical monitoring of personnel as required by both the CDC/NIH guidelines (CDC/NIH, 1999) and AR 385-69. Baseline serum samples (blood samples obtained before working with an etiologic agent) must be obtained from workers. CDC/NIH guidelines also recommend, and AR 385-69 requires, that additional periodic blood studies be conducted for those working with etiologic agents. OSHA regulations govern required training programs in bloodborne pathogens (Title 29 CFR 1910.1030), hazard communication (Title 29 CFR 1910.1200), and occupational exposure to hazardous chemicals in the laboratory (Title 29 CFR 1910-1450). The latter two citations are addressed in the USAMRIID *Chemical Hygiene Plan* (USAMRIID Regulation 385-30, 29 November 1999) (USAMRIID, 2001). USAMRIID Regulation 385-16, *Bloodborne Pathogens Exposure Control Plan*, dated 16 October 1998 establishes policies and procedures for an exposure control plan in accordance with requirements of 29 CFR 1910.1030. USAMRIID Regulation 385-16 is part of the *Safety Program Manual*. The SRPO provides training programs on bloodborne pathogens, respiratory protection, laboratory safety operations, positive pressure protective suit training, and radiation safety. The Logistics Division provides training for the hazard communication standard and the CHP. Personnel attend a newcomers' training briefing presented by the SRPO, Logistics Division, Company Commander, and Headquarters personnel. In addition, each division trains personnel in unique procedures (e.g., laboratory entry and exit, autoclave and centrifuge operation, and waste disposal). All training is recorded and updated in a *Minimal Essential Training Requirements* document (USAMRIID, 2000a).

PPE include gloves, respirators, goggles, face shields, and hearing protection as needed. In BSL-1 and BSL-2 areas, workers must wear a fully fastened laboratory coat. Personnel must wear special laboratory clothing in BSL-3/ABSL-3 and BSL-4/ABSL-4 areas and shower and change into street clothing prior to exiting biological containment areas. BSL-4/ABSL-4 workers wear a one-piece positive pressure protective suit ventilated by its own air supply system. Personnel use careful techniques and follow specialized guidelines to ensure maximum worker safety even when primary barriers are utilized. Practice using noninfectious or nontoxic materials is encouraged to determine what PPE and techniques are required to reduce the hazard potential of a study (USAMRIID, 2000a).

There are 192 personnel at USAMRIID authorized to enter BSL-3 containment areas, and 91 personnel authorized to enter BSL-4 containment areas (April 1, 2001 data). These personnel include researchers and technicians, and personnel providing operational support (facility engineering, medical maintenance, veterinary medicine, veterinary pathology, security, and safety) (USAMRIID, 2001). All USAMRIID personnel entering BSL-3 or BSL-4 suites are in a USAMRIID managed medical monitoring program and are enrolled in the SIP. The USAMRIID SIP vaccinates laboratory workers and support staff with investigational or licensed vaccines to protect individuals against infection with hazardous biological agents. Currently, 366 USAMRIID personnel are enrolled in the SIP protocols (January 4, 2001 data). In addition, there are 81 DIS personnel, and 6 Fort Detrick Fire Department personnel enrolled in the USAMRIID SIP. These latter 87 people provide operational support to the USAMRIID mission

(USAMRIID, 2001). SIP protocols meet both U.S. Food and Drug Administration (FDA) requirements for administration of Investigational New Drug (IND) vaccines and CDC/NIH guidelines. Vaccines when available are administered to workers at risk of exposure to etiologic agents prior to beginning work (USAMRIID, 2000a, 2000b; CDC/NIH, 1999). SIP participants are required to undergo complete medical evaluations and must receive medical clearance prior to vaccinations. Prior to vaccination, workers must be informed of possible adverse reactions to the vaccine and sign an informed consent document. The entry into SIP is considered equivalent to human clinical trial status, and participation is based on voluntary entry. Maintenance workers and engineering staff who occasionally must enter BSL-3 and BSL-4 facilities are protected by wearing the appropriate PPE in the same manner as laboratory workers and are also enrolled in the SIP and receive biosafety training. In addition, areas and equipment are decontaminated prior to being serviced by the maintenance and engineering staff. The Commander, USAMRIID authorizes entry into biological containment areas and any exception to the specific BSL-3 and BSL-4 area entry requirements. If respirator use is required, workers must be enrolled in a respiratory protection program to include medical clearance for the use of a respirator (USAMRIID, 2000a). Workers unable to undergo vaccination for medical reasons are not permitted to work with those agents for which there is a vaccine. These workers are not permitted entry into containment suites where the vaccinations are required (USAMRIID 2001). AR 385-69 requires ongoing monitoring of all personnel performing work for the DA that involves the use of etiologic agents. USAMRIID personnel receive annual medical surveillance that includes physical examinations, laboratory tests, and x-rays to monitor the program participants' health. Personnel undergo blood tests that monitor levels of immunity and potential exposures, and booster immunizations are administered as required (USAMRIID, 2000a).

Residual formaldehyde levels are monitored after decontamination with paraformaldehyde and neutralization with ammonium bicarbonate in accordance with USAMRIID Regulations 385-17 and 385-2. When formaldehyde levels fall below 0.5 parts per million (the action level according to OSHA) as determined by a formaldemeter, the area is declared safe for workers to enter (USAMRIID, 2000f).

2.8.2 Public Health and Safety and Emergency Services

In accordance with AR 385-69, USAMRIID must coordinate emergency preparedness with local emergency service providers and maintain formalized agreements describing the specifics of emergency support. The Fort Detrick Provost Marshall's Office provides emergency services to USAMRIID. These emergency services include fire and hazardous materials response. The Fort Detrick Fire Department provides emergency services including fire, emergency medical services, and hazardous materials response to USAMRIID. A Mutual Aid Agreement for the coordination of emergency medical services between the Army and Frederick County and the Frederick County Volunteer Fire and Rescue Companies was signed on 1 October 1998. The Frederick County Volunteer Fire and Rescue Association, Inc., represents the volunteers who provide local emergency medical services (USAMRIID, 2000a, 2000b, 2000d).

Fort Detrick Fire Department personnel are the first responders to USAMRIID for a medical incident requiring extraction of an individual from a laboratory area. Exercises are conducted each quarter with first responders to maintain their skills and continually familiarize them with the operations and configuration(s) of USAMRIID laboratories. Each exercise is conducted with

the assistance of medical personnel from the Medical Division, USAMRIID. Emergency service personnel from outside of Fort Detrick do not enter any USAMRIID laboratory areas. The Fort Detrick Fire Department will transfer an individual in medical distress to emergency service personnel who will then transport the individual to a local hospital (USAMRIID, 2001).

2.8.3 Accidents and Incidents

AR 385-69 requires that a hazard analysis and job safety evaluation be performed prior to work involving etiologic agents in the Biological Defense Program. This analysis must include examination of the maximum credible event (MCE) (see Section 5.2.10.3). The purpose of performing a hazard analysis is to carefully consider the range of potential consequences that might result from a mishap during each type of potentially hazardous activity performed. Such an analysis provides a way to assess whether existing safeguards are adequate to protect human health and the environment in the event of a mishap.

Accidents must be reported immediately as described in *USAMRIID Accident and Illness Reporting,* dated September 2000. In accordance with policy, USAMRIID's SRPO investigates all incidents, which are recorded on Form 1326-R, 1 March 1989 (*Fort Detrick Record of Occupational Injury/Illness/Incident of Potential Hazard Exposure*). Copies of the forms are sent to the USAG Safety Office and the individual's medical record (USAMRIID, 2000b). The USAMRIID *Safety Policy Regarding Illness Reporting by Employees*, dated 13 May 2000, details responsibilities and procedures for reporting exposures and potential exposures (USAMRIID, 2000f). USAMRIID has a medical support facility for the hospitalization and treatment of personnel who are exposed to etiologic agents, or who become ill from a suspected occupational disease (USAMRIID, 2000a).

Historically USAMRIID has had an excellent safety record. Since the last environmental assessment of USAMRIID in 1991, only one laboratory-acquired illness (LAI) has been reported at USAMRIID (although there was a 1994 situation wherein one person experienced symptoms suggestive of eye exposure to staphylococcal enterotoxin B (USAMRIID, 2000a), the cause of these symptoms could not be determined). The one LAI occurred in March 2000 when a scientist developed glanders (a disease that normally affects horses, mules, donkeys, and other domestic animals that is not communicable via casual person-to-person contact) from working with *Burkholderia mallei*. The individual was hospitalized but recovered after treatment with the appropriate antibiotics. USAMRIID conducted an investigation of the incident, which indicated that the scientist had contracted the disease from working ungloved in the BSL-3 laboratory, a violation of safety procedures. Another violation found was that the individual had delayed reporting his disease to his superiors. The investigative report, which was conducted with the assistance of State and CDC public health officers' input, contained a number of recommendations, which have been carried out by USAMRIID (USAMRIID, 2000h).

A safety stand-down was conducted for all USAMRIID personnel to reemphasize proper safety procedures and individual responsibility for working in the biocontainment laboratories and to ensure that laboratory personnel understand the risks and clinical illness for the organisms with which they work. Reporting procedures for potential mission agent exposures and illnesses were also reemphasized. Additional meetings were held with local and state public health authorities and the local hospital to foster improved communication between USAMRIID physicians and

local private physicians regarding potential occupational exposures. A safety task force was also established to take an in-depth look at all of USAMRIID's procedures to augment existing regulations and procedures to mitigate against the potential for laboratory-acquired infections and further reduce the potential for inadvertent breaches in biocontainment due to lapses in judgment or vigilance in adherence to engineering and operational controls.

2.8.4 Human Research Subject Protection

Human volunteers are an important part of the USAMRIID medical research effort. Studies may be conducted on an "outpatient" basis when it is determined that the risks are minimal. Inpatient studies require that human volunteers be admitted to the Clinical Research Ward. Research involving human subjects is conducted under the provisions of AR 70-25, *Use of Volunteers as Subjects of Research*, dated 25 January 1990; 32 CFR 219, *Protection of Human Subjects*; DoD Directive 3216.2, *Protection of Human Subjects in DoD-Supported Research*, dated January 7, 1983; USAMRIID Regulation 70-25, *Use of Human Subjects in Research*, dated 24 February 2000; 10 USC 980, *Limitation on Use of Humans as Experimental Subjects*; and FDA Regulations, 21 CFR 50, *Protection of Human Subjects*. USAMRIID activities also involve the use of human research subjects under the auspices of the SIP (CDC/NIH, 1999).

USAMRIID Regulation 70-25 describes the function of the Human Use Committee (HUC). USAMRIID's HUC reviews research protocols involving human subjects to ensure the scientific and ethical merits of the studies and to fully protect and safeguard the rights and welfare of human subjects. These protocols also are reviewed by USAMRMC and the Office of the Army Surgeon General.

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3.0 ALTERNATIVES CONSIDERED

3.1 Introduction

The proposed action and subject of this EA is to continue the current and currently planned activities at the USAMRIID facilities located at Fort Detrick in Frederick, Maryland (Alternative I, no action, the preferred alternative). During the preparation of this EA, two reasonable alternatives to the proposed action were identified. These alternatives were to conduct some or all of the current and currently planned activities at another facility (Alternative II) and to cease current and currently planned activities (Alternative III).

3.2 Alternative I – Continue Current and Currently Planned Activities at USAMRIID – No Action

Alternative I (no action) entails the activities necessary to continue the current and currently planned activities at USAMRIID. This alternative is preferred because the facilities and professional expertise available at USAMRIID significantly contribute to U.S. efforts toward medical defense against validated biological warfare threats and infectious diseases.

3.3 Alternative II – Conduct Some or All of the Current and Currently Planned USAMRIID Activities at Another Facility

Alternative II entails conducting some or all of the current and currently planned USAMRIID activities at another facility. This alternative is not the preferred alternative because conducting some or all of the current and currently planned USAMRIID activities at another facility does not offer significant advantage over the preferred alternative. Alternative II may require the renovation of a facility or the construction of a new facility, activities that will cause some adverse environmental impacts. In the event that renovation or new construction would not be required, the environmental impacts of Alternative II are likely to be similar to Alternative I (no action).

3.4 Alternative III – Cease Current and Currently Planned Activities at USAMRIID

Alternative III entails ceasing current and currently planned USAMRIID activities. Ceasing current and currently planned activities at USAMRIID will eliminate the negligible environmental impacts associated with the proposed action. Alternative III is not preferred because it will impede U.S efforts toward medical defense against validated biological warfare threats and infectious diseases.

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4.0 AFFECTED ENVIRONMENT

4.1 Introduction

This section of the EA describes aspects of the biophysical and socioeconomic environment (i.e., resource areas) that potentially could be impacted by implementing the proposed action.

4.2 Location and Physical Description

Fort Detrick is located in the northwest corner of the City of Frederick, Maryland. The installation covers 1,230 acres and consists of four noncontiguous parcels of land known as Areas A, B, and C (two parcels). USAMRIID is located on Area A and Area B west of Area A, which are in the north central portion of Frederick and are bounded on the north by the city limits. The City of Frederick covers 18.48 square miles in Frederick County (see Figure 4-1). The county covers approximately 664 square miles in north central Maryland (City of Frederick Planning Department, 1995).

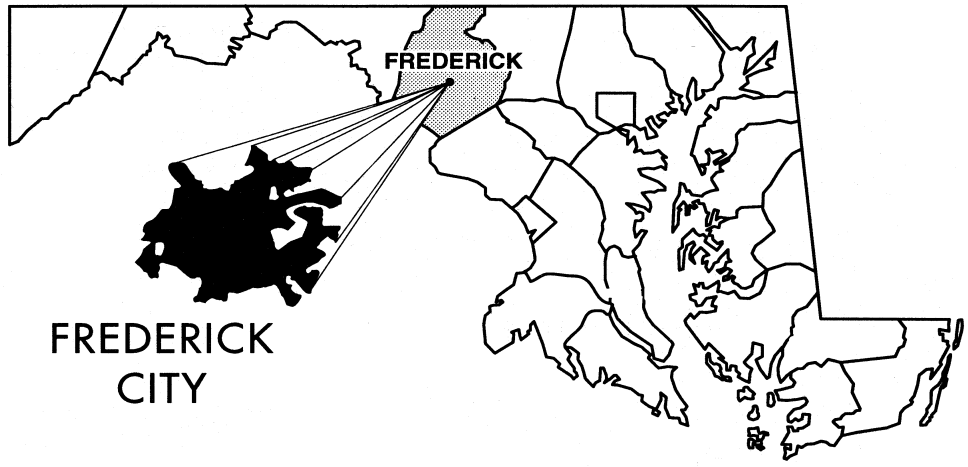

Figure 4-1. Location of Frederick, Maryland

4.3 Land Use

Current land use for the portion of Area A where USAMRIID (Buildings 1425 and 1412) and USDA (Building 1301) are located is Research and Development (see Section 2.2). The current land use for Area B is USAMRIID Animal Farm. Additional information about existing land use at Fort Detrick may be obtained from the EPG (USAG, 1998).

4.4 Climate

Frederick County has a temperate continental climate with four distinct seasons. The climate is characterized by short, warm summers and mild winters with occasional cold periods. The Catoctin Mountains, which run north-south approximately 5 miles west of Frederick, influence

the local weather conditions. The temperature range in Frederick County is from –12 degrees Fahrenheit (°F) in the winter to 109°F in the summer, with an average annual temperature of 54°F (International Station Meteorological Climate Summary, 1997). The average high temperature is 66ºF, and the average low temperature is 44ºF. Average annual precipitation is 40.4 inches. The average relative humidity is 65% (International Station Meteorological Climate Summary, undated). Thunderstorms occur most frequently in the summer. The average annual snowfall is 24 inches (DA, 1991). There were 14 reports of tornadoes in Frederick County between 1950 and 1998 (National Climatic Data Center, 1998). Prevailing winds are from the northwest from October through April and from the southwest from May through September. Local conditions are influenced by a large high-pressure system located over the ocean during the summer (Maryland Office of Environmental Programs, 1986).

4.5 Geology

Fort Detrick lies within the Western Division of the Piedmont physiographic province. The region is characterized by rolling topography with low ridges and stream valleys. This division extends west to the Blue Ridge District of the Appalachian Province, which includes the Catoctin Mountains. To the east, the Eastern Division of the Piedmont Province is divided from the Atlantic Coastal Plain by the Fall Line with its characteristic waterfalls or rapids. Frederick County lies in the uplands of the province. The low, rounded hills and shallow valleys are underlain by Paleozoic and Precambrian Age rocks. Less strongly metamorphosed and sedimentary rocks underlie the Western Division than the Eastern Division of the Piedmont Province. These rocks include the limestone Frederick Valley. In central Frederick County, Cambrian and Ordovician limestone and dolomite underlie the Frederick Valley (Edwards, Jr., 1981; Maryland Office of Environmental Programs, 1986; Trapp, Jr. and Horn, 1997).

Between 1758 and 1993 there were 47 reported earthquakes in Maryland. In addition, Maryland experiences effects of earthquakes with epicenters in other states. However, there is a low probability risk (i.e., a very low chance of experiencing a damaging earthquake in a 50-year period) of an earthquake in Maryland (Reger, 1987).

4.6 Soils

Piedmont Province soils are productive for agricultural purposes (Maryland Office of Environmental Programs, 1986). The soils of Frederick County, some of the most productive in Maryland, are composed of a combination of residual limestone soils and wind-dispersed soils. The Duffield series soils, which have a low to moderate water holding capacity, are the most extensive of soils located in the Frederick Valley. These soils are fertile, productive, and manageable with the potential to support a variety of vegetation including grasses, wetlands plant species, trees, and agriculture (U.S. Army Environmental Center [USAEC], 1997).

4.7 Water Resources

4.7.1 Surface Water

The Fort Detrick Water Treatment Plant withdraws water from the Monocacy River under Water Appropriation Permit number FR43S001. Annual water usage for Fort Detrick is 454,296,000 gallons. USAMRIID uses 60,028,000 gallons per year, which is approximately 13% of the total annual water usage for Fort Detrick (USAMRIID, 2000c, 2000d).

USAMRIID generates about 43,820,000 gallons of wastewater annually, about 13% of Fort Detrick's total wastewater of 347,190,000 gallons per year. Additionally, USAMRIID produces 24,802,000 gallons of potentially contaminated wastewater that drains to the dedicated LSS. In accordance with DA Pamphlet 385-69 and CDC/NIH guidelines, BSL-4 wastewater is decontaminated before it enters the dedicated LSS. LSS wastewater is treated at the Fort Detrick SSP prior to discharge into the sanitary sewer system (USAMRIID, 2000c; USAG, 1998). A leak exists in the system near the Fort Detrick Steam Sterilization Plant; however, DIS has a contract in place to replace the leaking dedicated laboratory sewer system (USAMRIID, 2000b). Wastewater in the sanitary sewer system is treated at the Fort Detrick WWTP and is discharged to the Monocacy River. There are point source discharges to the Monocacy River other than Fort Detrick, including the City of Frederick. Due in part to agriculture and urbanization, the potential for sediment loading in the river is high.

The land underlying Fort Detrick, and therefore USAMRIID, drains into Carroll Creek and ultimately the Monocacy River. Carroll Creek, a tributary of the Monocacy River, originates approximately 2 miles west of Frederick in the Catoctin Mountains, flows between Area A and Area B, and empties into the Monocacy River. The Monocacy River originates at the Maryland-Pennsylvania border, flows south, and empties into the Potomac River approximately 15 miles south of Frederick. The State of Maryland designates the Monocacy River as Recreational Trout Waters and Public Water Supply (Use IV-P) (Code of Maryland Regulations [COMAR] 26.08.02). Use IV-P waters include waters with the potential for or that are suited for adult trout. These waters are managed as special fisheries by periodic stocking and seasonal catching. Uses of the river include water supply, agricultural irrigation, boating, canoeing, and recreational fishing.

4.7.2 Groundwater

Carbonate rock aquifers, including the Frederick Limestones, are located in the Frederick Valley area. These limestones yield large volumes of water to wells. Typical well yields in the Frederick Limestone are 120-170 gallons per minute, and yields may be up to 275 gallons per minute locally. Factors affecting well yield include the well location, the type of rock, thickness of the regolith (an unconsolidated layer of fragmented, weathered bedrock and alluvium lying on unweathered bedrock), and characteristics of the bedrock fractures (Maryland Office of Environmental Programs, 1986; Trapp, Jr. and Horn, 1997). Groundwater discharges directly into streams from the bedrock or into regolith or as springs and seeps, or by evapotranspiration (U.S. Geological Survey (USGS), 1996; Trapp, Jr. and Horn, 1997). Groundwater quality in the Piedmont Province is generally good, and is suitable for drinking and other uses (Trapp, Jr. and

Horn, 1997). The potential for contamination is high due to the highly interconnected fractures (Maryland Office of Environmental Programs, 1986).

The groundwater gradient in and around the Area A slopes to the southeast, averaging about one half of a degree. A remedial investigation at Fort Detrick revealed elevated trichloroethylene (TCE), a suspected carcinogen, and volatile organic compound (VOC) levels in Area A groundwater. These contaminants were found in highest concentrations near the Building 568 TCE spill site and at lower levels throughout Area A. These compounds in the groundwater do not pose a health risk to residents at Fort Detrick because groundwater is not used for human consumption on the Installation. More details regarding groundwater contamination levels at Fort Detrick can be obtained from the *Revised Final Fort Detrick Remedial Investigation Report, Area A*, dated June 2000 (U.S. Army Corps of Engineers, 2000). Additional information about groundwater at Fort Detrick is provided in the EPG (USAG, 1998).

The water table in Area B fluctuates as much as 25 feet during the spring, and ranges from 4.5 feet in March to 47 feet in October (DA, 1991). Groundwater flow is partially restricted by the fault that transects Area B. Area B-11 on Area B is the primary source of groundwater contamination and the subject of an ongoing remedial investigation at Fort Detrick. TCE was detected in a groundwater-monitoring well located near the southeastern border of Area B in March 1991. In October 1992, MDE and the Frederick County Health Department sampled drinking water supplies of seven households near Area B. Contamination was detected in some of the sampled wells. Concentrations of TCE and/or tetrachloroethylene (PCE), also a suspected carcinogen, in two wells exceeded maximum contaminant levels (MCLs) established by the USEPA. The affected households were provided with bottled drinking water until they were connected to the City of Frederick water supply. Testing by the MDE and the Frederick County Health Department detected levels of TCE, PCE, and other VOCs in 16 of 33 wells sampled around Area B, including four levels of contamination at or exceeding MCLs. Subsequently, a full investigation of the contamination in Area B was initiated (MDE, 1993). Details of the contamination and remedial efforts are provided in the EPG (USAG, 1998).

4.8 Plant and Animal Ecology

Much of the native vegetation of the Frederick area has been altered or destroyed due to urbanization. Three types of natural vegetative communities exist on the installation, including grasslands, upland forest, and wetland/riparian. Fort Detrick currently manages approximately 500 acres of pasture, forested area, grasslands, and agricultural fields. This area was originally covered by oak-hickory, hardwood forests. A list of natural and introduced vegetative species at Fort Detrick may be found in Appendix 1 of the EPG (USAG, 1998).

The *Draft Integrated Natural Resource Management Plan* (INRMP) was prepared for Fort Detrick in accordance with AR 200-3 (*Environmental Quality Natural Resources-Land, Forest and Wildlife Management*, Chapter 9) and other applicable laws and regulations. A description of the natural resources of the installation as well as direction for future management is included in the Draft INRMP (USAG, 1997b).

Fort Detrick has very little wildlife habitat remaining due to extensive urbanization. As a result, the existing wildlife populations such as white-tailed deer, raccoon, gray squirrel, fox squirrel,

and opossum are characteristic of those found in urbanized environments. Species common to oak-hickory hardwood forests potentially occur on the installation (USAG, 1997c). Lists of bird species observed on the installation and mammal species potentially inhabiting Fort Detrick may be found in appendices of the EPG (USAG, 1998).

The official State Threatened and Endangered Species List is contained in COMAR 08.03.08, the State Threatened and Endangered Species regulations. There are no records of Federal or state listed rare, threatened, or endangered species of plant or animals occurring on Fort Detrick (Slattery, 1997).

4.9 Wetlands

Wetlands are transitional lands between terrestrial and deep-water habitats that provide environmental benefits, such as wildlife habitat, water quality protection, and flood control, and have economic value. Wetlands are classified on the basis of their hydrology, vegetation, and substrate (USGS, 1996).

During the 1989 *Stormwater Management and Erosion and Sediment Control Study* (Greenhorne and O'Mara, 1990), five sites at Fort Detrick were characterized as upland wetlands; however, these sites were not delineated. A complete wetlands delineation will be conducted by the U.S. Fish and Wildlife Service (USFWS) in the future. Information regarding the wetland areas is taken from the 1989 investigation (as cited in DA, 1991). Wetland area W-5, the most productive wetland at Fort Detrick, is associated with the Nallin Farm Pond and its spillway that are located in the northeastern corner of Area A. Wetland area W-4 was located in the southeast corner of Area A. This area is no longer considered a jurisdictional wetland. The three remaining wetland areas are located in Area B. Wetland area W-3 is located on the eastern edge of Area B in a riparian area associated with a tributary of Carroll Creek. Wetland area W-2, located along Carroll Creek on the southern border of Area B, is managed as a riparian buffer and planted with trees. Wetland area W-1 is located in the south-central portion of Area B (USAG, 1998).

4.10 Air Quality

Meteorological conditions and the location and size of pollution sources contribute to air quality. Under the Clean Air Act (CAA), the USEPA adopted the National Ambient Air Quality Standards (NAAQS) to control a select group of widely occurring pollutants and establish safe concentration levels for each criteria pollutant. The NAAQS criteria pollutants include carbon monoxide (CO), nitrogen oxides (NOx), sulfur dioxide (SO_2), ozone (O_3), lead (Pb), and particulate matter less than or equal to 10 microns in aerodynamic diameter (PM_{10}). In July 1997, the USEPA added an annual $PM_{2.5}$ (i.e., particulate matter less than or equal to 2.5 microns in aerodynamic diameter) standard of 15 micrograms per cubic meter and a 24-hour $PM_{2.5}$ standard of 65 micrograms per cubic meter. The current 1-hour O_3 primary standard was replaced with an 8-hour O_3 standard. Areas not meeting the NAAQS are designated as "nonattainment" areas.

Fort Detrick lies within the Central Maryland Air Quality Control Region (Area II). The air quality of Frederick County is regulated by MDE's Air and Radiation Management Administration that monitors air quality, establishes standards, and implements regulations. Maryland is in attainment for all criteria pollutants except O_3. Overall, the air quality of Frederick County, including Fort Detrick, is good. Frederick County is located within the Washington, DC Metropolitan Area that was in serious nonattainment for O_3 in 1999 (Stahl, 2000). This designation is primarily based upon emissions from vehicular traffic in the area, which cause O_3 concentrations to periodically exceed the NAAQS during warm weather months.

USEPA regulations require and 40 CFR 68 (*Chemical Accident Prevention Provisions)* and Title I Part A Section 112(r) of the CAA Amendments of 1990 mandate Fort Detrick's Risk Management Plan (RMP). The Installation must have an RMP because it stores threshold quantities of chlorine, which requires a program to reduce the possibility of the chemical being released into the air. It has been determined that USAMRIID does not store threshold quantities of any of listed chemicals, including chlorine, that require RMPs (Wolf, 2000).

4.11 Historical and Cultural Resources

Historical and cultural resources include historic sites, architecturally important buildings, and unique geological locations. Protection of these resources is mandated by the National Historic Preservation Act of 1966, as amended (Public Law (PL) 89-665), and implemented by the DA through NEPA, AR 200-2, and AR 200-4 (*Cultural Resources Management*).

Developed in cooperation with the Maryland Historical Trust, Fort Detrick maintains an Historic Preservation Plan that includes the classification of select structures and sites on the installation according to potential historic significance and identifies appropriate treatments and maintenance requirements for preservation. A detailed description of the history of Fort Detrick, including sites listed on the National Register of Historic Places (NRHP), can be found in the EPG (USAG, 1998).

Buildings 1412 and 1414 are both considered exceptionally significant. Building 1412 was a special operations building uniquely designed to support its biological warfare research mission prior to 1969. Building 1414 was constructed adjacent to Building 1412 as the former was designed to sterilize, by incineration, the exhaust air from Building 1412. These buildings are considered exceptionally significant as an example of the Army's Cold War policies under the themes of research, development, and logistics (Criterion A). Although the architecture is not the work of a master, the buildings and other supporting structures are all related to the Cold War mission since they were specifically designed to house the Army's biological warfare program, a program which was central to the Cold War (Criterion C). Fort Detrick is one of two facilities in the U.S. designed specifically for the research and development of biological warfare elements by the Army. Since biological warfare was a central element in the Cold War arsenal, these buildings provide information regarding that aspect of American Military History and therefore are eligible for the NRHP under Criterion Consideration G (USAMRIID, 2001).

4.12 Energy Resources

Energy resources used by USAMRIID activities include electricity, steam, natural gas, fuel oil, and diesel fuel. Allegheny Power supplies electricity to Fort Detrick. Current annual electricity usage at USAMRIID is 10,594,000-kilowatt hours (kWh). The annual usage for Fort Detrick is 140,361,000 kWh. USAMRIID uses approximately 7.55% of the total Fort Detrick consumption. USAMRIID facilities are heated by 120,818,000 pounds of steam annually, which is 19.54% of the 618,380,000 pounds annually generated by the Fort Detrick Central Boiler Plant. Natural gas is obtained from Washington Gas. USAMRIID currently uses 927,100 cubic feet of natural gas annually or approximately 0.15% of Fort Detrick's annual consumption of 613,761,600 cubic feet of natural gas. Annually, USAMRIID uses 1,465 gallons of fuel oil supplied by Griffin Consumers, Inc. This constitutes 0.70% of the 209,457 gallons per year of fuel oil used by Fort Detrick. Griffin Consumers, Inc. also supplies the 63,964 gallons of diesel fuel used annually by Fort Detrick. USAMRIID uses 1,632 gallons or 2.55% of the annual total quantity of diesel fuel consumed (USAMRIID, 2000b, 2000c).

4.13 Socioeconomic Environment

USAMRIID employs 558 people: 219 military, 233 civilian, and 106 contract employees (USAMRIID, 2000a). The total population (people who live or work at Fort Detrick) of Fort Detrick is 6,166. Of this number, 400 people both live and work on the installation. There are 281 children under 18 years old living at Fort Detrick. A day care center situated on the installation provides care for 128 children (Springer, 1999).

According to the U.S. Census Bureau, the population of Frederick City was 40,148 in 1990. The city's population increased 15,300 (54.5%) between 1980 and 1992. In 1990, the median age of Frederick residents was 31 years. Of those 25 years of age and over, 77.9% had graduated from high school and 24% had obtained a bachelor's degree. The median household income was $34,891 in 1989. In 1991 the unemployment rate for Frederick was 6.9%.

According to the 1990 U.S. Census (U.S. Census, 1990), the breakdown of occupations in Frederick was as follows: managerial and professional (27.0%); technical, sales, and administrative support (36.9%); service occupations (12.6%); farming, forestry, and fishing (1.2%); precision production, crafts, and repair (12.0%); and operators, fabricators, and laborers (10.2%). Frederick's population was 84.2% white, 12.8% black, 1.9% Asian or Pacific Islander, <1% American Indian, Eskimo, or Aleut, and <1% other. In 1990, 8.0% of persons with income in Frederick lived below the poverty level (U.S. Census Bureau, 1990; University of Virginia Library of Social Sciences Data Center, 1998).

4.14 Noise

Since the 1991 EA, there have been no citizen complaints regarding noise originating from USAMRIID (USAMRIID, 2000a).

4.15 Odors

Since the 1991 EA, there have been no citizen complaints regarding odors originating from USAMRIID (USAMRIID, 2000a).

4.16 Transportation

Fort Detrick is located in the northwest portion of Frederick, Maryland, approximately 45 miles north of Washington, DC and 45 miles west-northwest of Baltimore, Maryland. Fort Detrick is accessible via a number of interstate and U.S. highways including I-70, I-270, U.S. 40, and U.S. 15. These major roadways and interstates provide convenient access from the City of Frederick to Washington, DC, Baltimore, and other employment centers in the region. Local access to the installation is via the surrounding roadway network of city streets, county roads, and state highways. U.S. 15, also known as the Frederick Bypass, is a two-lane divided highway serving both regional and local commuter traffic in Frederick. This highway is located approximately 0.5 miles south of Area A. The Frederick Bypass interchanges with Rosemont Avenue, West Seventh Street, and Opossumtown Pike. Rosemont Avenue is a major north-south artery in Frederick and serves as the western boundary of Area A. West Seventh Street, a minor north-south artery, is the primary access route to Area A. Opossumtown Pike, a major north-south artery, forms the eastern border of Area A. Military Road, an east-west minor arterial, serves as the southern boundary of Area A.

The Frederick Bus System east-west Blue Route provides local bus service to Fort Detrick and access to the Maryland Rail commuter station in downtown Frederick. The City of Frederick is not serviced by a railway system; however, rail terminals are located in Washington, DC and Baltimore. The Baltimore-Washington International Airport, Dulles International Airport, and Reagan National Airport provide commercial airline service to passengers in the region. The Hagerstown Municipal Airport offers limited passenger and cargo air service. Frederick Municipal Airport, located approximately 3 miles east of Area A, serves private aircraft users.

4.17 Public Opinion

There are no records of citizen complaints regarding USAMRIID. Public opinion regarding the facility has been favorable since the 1991 EA (USAMRIID, 2000e).

5.0 ENVIRONMENTAL CONSEQUENCES

5.1 Introduction

In this section, the potential for significant environmental impacts (direct, indirect, and cumulative) likely to result from continuing the current and currently planned activities at USAMRIID will be discussed. This discussion will identify cause and effect relationships between the proposed action and impacts to the environment, including examining impacts that may not necessarily occur but that are reasonably predictable. The term "consequence" refers to the outcome of an event or events without considering probability. Where possible, potential events will be characterized in terms of both their potential consequence and the probability (likeliness) that they will occur.

5.2 Environmental Consequences

5.2.1 Land Use, Geology, and Soils

It is highly unlikely that implementing the proposed action (Alternative I, no action) would impact land use patterns, geology, or soils in Frederick. All proposed activities will be conducted in existing facilities that have been sited in conformance to local topography and in accordance with local ordinance governing land use. There will be no on-site disposal of wastes resulting from the proposed action (see Section 2.6).

The quantity of wastes disposed of in the Fort Detrick landfill will be a minor component of the total wastes for the installation. USAMRIID contributes less than 7% to the total general solid waste of Fort Detrick (331,460 pounds/4,983,136 pounds x 100 = 6.65%).

Agricultural resources in Frederick have been depleted as the result of progressive urbanization within the region. USAMRIID activities do not impact agricultural resources on Fort Detrick and are consistent with land use patterns for the installation (USAG, 1998).

Implementing Alternative II in a manner consistent with Federal, state, and local laws and regulations would likely result in negligible impacts similar to those anticipated from the implementation of Alternative I (no action). If implementing Alternative II included renovation or construction, the adverse environmental impacts to land use, geology, and soils would likely be negligible to minor. Implementing Alternative III would eliminate any negligible impacts to land use patterns, geological resources, or soils associated with Alternative I (no action).

5.2.2 Air Quality

It is likely that implementing the proposed action (Alternative I, no action) will result in negligible negative impacts to air quality in the Frederick regional area. The proposed activities have the potential to impact air quality through incineration of waste materials; by consuming the energy resources required to power ventilation systems and other facility safety features; by the vehicular emissions generated by personnel, suppliers, and shipping activities; and by air emissions generated on site. Wastes at USAMRIID, after being rendered innocuous as required, will be incinerated at Fort Detrick. Permit restrictions take into account existing local air quality

conditions (see Section 2.6). Current regional air quality in Frederick is good except for nonattainment status for O_3 (see Section 4.10). Because formaldehyde gas used during laboratory decontamination will be neutralized with ammonium bicarbonate prior to exhausting the laboratory air to the atmosphere, no adverse impacts to air quality are anticipated.

Implementing Alternative II would likely result in comparable minor impacts to air quality at another location. Implementing Alternative III would eliminate the minor impacts associated with the proposed action.

5.2.3 Water Resources and Wetlands

Implementing the proposed action (Alternative I, no action) is unlikely to significantly impact water resources near USAMRIID. USAMRIID contributes approximately 13% to the total sanitary wastewater load of Fort Detrick (43,820,000 gallons/347,190,000 gallons x 100 = 12.6%). The majority of the installation's contaminated wastewater is generated by USAMRIID (24,802,000 gallons versus 25,073,000 for all of Fort Detrick). Adherence to Federal and state law regulating waste disposal mitigates potential impacts to surface water resources. Adverse impacts to wetlands from implementing the proposed action (Alternative I, no action) are highly unlikely as the proposed action will be conducted in existing facilities and no construction related to the proposed activities is planned or anticipated; therefore, stormwater runoff patterns will not be altered and there will be no disturbance of existing wetlands. Wastewater will not be discharged to wetlands.

If conducted at facilities with similar controls, implementing Alternative II would likely result in negligible impacts similar to those of the proposed action. Implementing Alternative III would eliminate the negligible impacts associated with implementing the proposed action.

5.2.4 Plant and Animal Ecology

It is unlikely that adverse impacts to plant or animal ecology will result from the conduct of the proposed activities (Alternative I, no action). No construction or renovation is planned that could impact plant or animal habitat. The etiologic agents that will be used in activities do not cause plant disease. Impacts to animals inhabiting areas near the facilities are highly unlikely because of the design of the physical facilities and the containment procedures and practices employed by USAMRIID. The facilities in which laboratory animals exposed to etiologic agents will be housed have barriers that reduce the likelihood of animal escape. Among these features are self-closing doors, sealed wall penetrations, lack of windows, and systems that are species-appropriate. In the unlikely event that an animal escaped, it would be unlikely to survive in the natural environment. The BDRP FPEIS evaluated this scenario and found that the probability that an animal bred for laboratory research could escape from a BSL-3 facility and survive in the wild was extremely remote. No such escapes have been recorded (DA, 1989).

Impacts potentially associated with implementing Alternative II would likely be similar to those of Alternative I (no action). Alternative III would eliminate any potential adverse impacts to local plant and animal ecology.

5.2.5 Historical and Cultural Resources

Adverse impacts to historical or archaeological resources are unlikely to result from implementation of the proposed action at USAMRIID. The proposed action will be conducted indoors in existing facilities that have been designed for their intended use. No renovation or construction is planned that would negatively impact resources. Although Buildings 1412 and 1414 are considered exceptionally significant historical resources and are eligible for the NRHP, implementation of the proposed action is unlikely to impact these resources. Similar activities have been conducted at USAMRIID for more than 30 years without appreciable negative impacts to either Building 1412 or Building 1414.

Conducting the proposed action at another location (Alternative II) is also unlikely to significantly impact historical or cultural resources unless renovation or new construction would be required and historical or cultural resources were present at the site. Implementing Alternative III would eliminate any potential for adverse impacts on historical or archaeological resources.

5.2.6 Energy Resources

Negligible impacts to energy resources are likely to result from implementing the proposed action at USAMRIID. The proposed activities will be conducted in existing facilities in which similar activities are currently conducted; however, the operation of the redundant ventilation systems required to maintain directional airflow requires energy resources in excess of those required for ventilation in noncontainment laboratories. This energy usage, however, is not likely to significantly impact energy resource consumption within the region.

Implementing the proposed action at another facility (Alternative II) would likely result in similar impacts to energy resources. Implementing Alternative III would eliminate these negligible impacts on energy resources.

5.2.7 Socioeconomic Environment and Aesthetics

It is unlikely that implementing the proposed action (Alternative I, no action) at USAMRIID will result in any significant adverse socioeconomic or aesthetic impacts. Implementing the proposed action will result in negligible positive socioeconomic impacts from employment opportunities and the acquisition of goods and services needed to maintain facilities and conduct proposed activities. Proposed USAMRIID activities may generate odors through the required heat treatment (sterilization) of contaminated or potentially contaminated materials or the preparation of culture materials. These odors, however, are transitory and rapidly diluted in the atmosphere. There have been no reports of citizen complaints concerning odors emanating from USAMRIID since the 1991 EA (USAMRIID, 2000a).

The activities associated with implementation of the proposed action do not inherently produce excessive levels of noise. It is unlikely that implementing the proposed action will adversely impact the noise levels of the area. There have been no citizen complaints concerning noise emanating from USAMRIID since the 1991 EA (USAMRIID, 2000a).

The negligible positive socioeconomic impacts and negligible aesthetic impacts associated with conducting the proposed USAMRIID activities at another facility (Alternative II) would likely be similar to the proposed action. Implementing Alternative III would eliminate the negligible positive impacts to the local economy and negligible aesthetic impacts likely to result from implementing the proposed action.

5.2.8 Transportation

Implementing the proposed action (Alternative I, no action) will likely have negligible impacts on transportation resources in the Frederick region. Local and/or regional traffic patterns and volumes will not likely be impacted by commuting workers or the traffic generated by vendors and visitors to the facility. Existing roads at Fort Detrick and parking facilities at USAMRIID are adequate to accommodate the anticipated level of traffic.

Transportation of etiologic agents to and from USAMRIID must be conducted in accordance with all applicable regulations, including AR 385-69. These regulations have been promulgated to protect the workers engaged in handling and/or shipping etiologic agents. The BDRP FPEIS concluded that storage and transport of etiologic agents did not pose a credible risk to the environment (DA, 1989). There have been no cases of illness associated with the transport of etiologic agents (World Health Organization, 1997).

Implementation of Alternative II may result in adverse impacts on transportation at another geographic location depending upon the transportation system. Implementation of Alternative III will eliminate any negligible impacts on transportation resources or from handling and shipping etiologic agents associated with the proposed action.

5.2.9 Public Opinion

Public opinion has been an issue in the conduct of biological warfare defense research and development activities and was extensively discussed in the *Joint Vaccine Acquisition Program Final Programmatic Environmental Assessment* (Joint Program Office for Biological Defense, 1997). There is strong congressional and public support for DoD policy of providing service men and women with the best possible protection against biological warfare agents. Potential criticisms, however, include the perceived potential for such activities to be used for offensive purposes, the safety and efficacy of biological defense vaccines, distrust of the military, and whether the military should be involved in vaccine development. Some public concerns relate to the existence of biological defense programs *per se*; others, to the intent, need for, and benefits of such programs. Some concerns are specific to the impacts of actions, such as the use of animals. Concerns such as these are not unique to the proposed USAMRIID activities but are concerns associated with biomedical research and development activities in general.

The government and its facilities (e.g., USAMRIID) do not engage in work related to the production or use of offensive biological weapons. Such activities are prohibited by the *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction* (the Biological Weapons Convention of 1972) to which the U.S. is a signatory. The prohibitions are enforced by Federal law that provides criminal penalties for biological weapons activities.

Biomedical research, development, testing, and evaluation (RDT&E) directed toward biological defense and the development of medical countermeasures have been examined within the context of NEPA. The environmental analyses conducted to date have identified no significant adverse environmental impacts associated with such work at the sites examined. Site-specific assessments conducted include the *U.S. Army Medical Research Institute of Chemical Defense Environmental Assessment* (USAMRICD, 1992), *Walter Reed Army Institute of Research Environmental Assessment* (WRAIR, 1993a), the *Walter Reed Army Institute of Research Leased Facilities Environmental Assessment* (WRAIR, 1993b), and the *BSL-2 Vaccine Facility at the Walter Reed Army Institute of Research at Forest Glen, Maryland Environmental Assessment* (WRAIR, 1994). The impacts on public opinion are likely to be minor regardless of the alternative implemented.

5.2.10 Human Health and Safety

The proposed action involves laboratory and animal test and evaluation studies, some of which will require the use of etiologic agents capable of causing human disease. A list of biological agents used at USAMRIID is provided in Section 2.3.

Risks to public health and safety and worker health and safety are mitigated by carefully considered and applied safety/biological containment procedures and practices. Decontamination of all potentially infectious liquid, air, and solid wastes prior to disposal prevents release of etiologic agents to the environment. The effectiveness of environmental engineering and work practice controls to contain and isolate etiologic agents from the laboratory environment and workers has been demonstrated. A limited number of LAIs have been recorded in a broad range of laboratories throughout the U.S. (CDC/NIH, 1999; Sewell, 1995). There have been no instances of infection or disease resulting from the conduct of these types of activities in communities adjacent to facilities such as USAMRIID.

5.2.10.1 Public Health and Safety

The risk to public health from the conduct of the proposed USAMRIID activities is extremely small. Because of laboratory procedures and the redundant engineering safety features required of biological containment facilities, it is highly unlikely that the public would be exposed to viable etiologic agents originating from USAMRIID. Adherence to Federal and state regulations pertaining to the safe handling and disposal of hazardous chemicals and potentially infectious material further mitigates the likelihood of impact to public health and safety.

Conducting the proposed activities at another facility (Alternative II) would also result in negligible risk to public health and safety. Implementing Alternative III would eliminate the negligible impact to public health and safety associated with the conduct of the proposed activities but would also eliminate the potential for positive impact to efforts toward medical defense against validated biological warfare threats and infectious diseases.

5.2.10.2 Occupational Health and Safety

Significant adverse impacts to the health and safety of laboratory workers are not anticipated as the result of conducting the proposed activities at USAMRIID (Alternative I, no action). Implementing Alternative I (no action) at USAMRIID requires using etiologic agents that are

capable of causing human disease and requires the use of laboratory animals that may be infected with etiologic agents transmissible to humans. The inherent risks associated with implementing the proposed action are minimized by implementing the environmental engineering and work practice controls described in the FSP, CDC/NIH guidelines (CDC/NIH, 1999), AR 385-69, DA Pamphlet 385-69, and numerous other Federal, state, and local regulations.

Environmental engineering controls that meet or exceed CDC/NIH guidelines (CDC/NIH, 1999) prevent etiologic agents from contaminating the laboratory environment. Risk of human exposure is further mitigated by the use of required laboratory work practices designed to reduce the potential for aerosol production during routine activities. Work practice controls used to prevent contamination of environments external to the biological containment laboratories include disinfecting work surfaces, floors, and drains and segregating and autoclaving waste materials, work clothes, and other material prior to removal from containment facilities. In addition to the use of engineering and work practice controls to reduce the risk of exposure to etiologic agents, regular medical monitoring is required of those employees engaged in work with etiologic agents. Prior to working with etiologic agents, individuals are required to undergo vaccination with available vaccines as part of the SIP. Significant impacts to worker health resulting from similar work have not been observed. Since 1991 only one case of a LAI has been reported at USAMRIID. The worker fully recovered after antibiotic treatment (see Section 2.8.3).

Performing the proposed activities at another facility (Alternative II) would result in similar minor to negligible impacts to worker health and safety. Implementing Alternative III would eliminate the minor impacts to worker health and safety associated with the conduct of the proposed activities.

5.2.10.3 Accidents and Incidents

In accordance with requirements of AR 385-69, MCE analyses have been developed for the proposed activities at USAMRIID. MCE analyses are performed to assess the range of possible consequences that could arise as the result of mishaps. The purpose of performing these analyses is to estimate the effectiveness in existing safeguards. Safeguards include such features as the engineering controls and the attributes of facility design that prevent the release of etiologic agents from the facility. An MCE is a realistic worst-case scenario to which credible information about existing safeguards is applied. In this EA, MCE analyses are used to examine the potential adverse impacts to human health and the environment from accidents related to the proposed work at USAMRIID. The probabilities of such accidents occurring are more remote given the operational and facility safeguards required and to date there have been no such incidents associated with similar activities at USAMRIID.

The first MCE scenario involves a BSL-3 laboratory accident during the processing of 1 liter (l) of a slurry containing *Coxiella burnetii* to prepare an experimental vaccine. During this process, a centrifuge rotor holding six 250-milliliter (ml) polyproplene centrifuge tubes is fitted with O-rings, and each tube contains 165 ml of slurry. The 990 ml of slurry contain a total of 9.9 x 10^{12} (9.9 trillion) HID_{50} (dose which infects 50% of exposed humans) of the organism.

In this scenario, the laboratory worker fails to use rubber O-rings to seal the centrifuge tubes, and all six tubes leak into the rotor cups. Because the worker also fails to properly tighten the safety

centrifuge caps designed to prevent a leak, some of the slurry leaks into the centrifuge compartment that houses the rotor. This compartment is not sealed against the release of organisms in a small particle aerosol. It is assumed that 10% of the slurry leaks, of which 99% remains within the rotor cups and does not aerosolize. Of the 1% which enters the centrifuge cabinet, only a fraction (0.1%) is aerosolized, and of that which is aerosolized, it is assumed that 90% settles as liquid droplets on the inside of the chamber.

The most serious consequence of this laboratory accident would be the release of enough infectious doses to override the air filter system, allowing the subsequent release of a concentrated aerosol into the surrounding community. Therefore, it is necessary to calculate the maximum number of aerosol infectious doses presented to the filter. This scenario assumed that the total initial HID_{50} are 9.9×10^{12}. Of the 10% of the HID_{50} which leaked from the tubes, 99% remained in the rotor cups. Of the 1% of the doses which leaked out of the cups, 0.1% were aerosolized by the rotor, and of these doses aerosolized, 90% remained in the liquid droplets that settled on the inside of the chamber. Thus, 10% (leaked from tubes) x 1% (leaked from rotor cups) x 0.1% (aerosolized) x 10% (did not settle out) equals 0.0000001% aerosolized HID_{50} released into the room. Thus, 0.0000001% x 9.9×10^{12} initial HID_{50} equals 9.9×10^{5} HID_{50} aerosolized.

Assuming the air filter system is 95% efficient, approximately 5×10^{4} HID_{50} were released from the exhaust stack. Using a simple Gaussian plume dispersion model, there would be less than one HID_{50} of *Coxiella burnetii* at a distance less than 2 meters from the stack.

The second MCE analysis involves type A botulinum toxin. This scenario assumes that a 250-ml centrifuge tube contains 240 ml of a solution containing toxin at a concentration of 2×10^{9} mouse (M) intraperitoneal (IP) LD_{50} ($MIPLD_{50}$ per ml of 50% pure type A botulinum toxin). One $MIPLD_{50}$ equals the amount of toxin required to cause death in 50% (LD_{50}) of mice injected IP. The LD_{50} dosages used in toxin solution challenges in mice are very different from the toxin aerosol exposures in humans (human respiratory). It is estimated that the concentration of an aerosolized solution of botulinum toxin that results in one human respiratory LD_{50} ($HRLD_{50}$) corresponds to a toxin solution concentration of 2.38×10^{3} injected IP into a mouse ($MIPLD_{50}$) (i.e., the human dose is estimated at about 2,400 times greater than the mouse dose required to produce the same effect).

During this scenario, a centrifuge tube breaks during centrifugation in a centrifuge located in a Class II BSC, releasing the toxin-containing solution within the rotor of the centrifuge. Most (99%) of the solution remains unaerosolized within the covered rotor while the rotor generates an aerosol of the remaining 1%. Of that which aerosolizes within the centrifuge cabinet, 90% settles as liquid droplets on the inside of the chamber. Assuming the aerosolization efficiency of 0.04%, 0.1 ml (0.0004 x 240) of the toxin solution is aerosolized into 1 to 5 micron particles. This 0.1 ml of solution contains approximately 8.4×10^{4} $HRLD_{50}$ ($0.1 \times 2 \times 10^{9} / 2.38 \times 10^{3}$). With an inward face air velocity of at least 75 feet per minute at the work opening of the Class II BSC, essentially all of the aerosol passes through the BSC's HEPA filters (99.97% efficiency). The aerosol containing 25.2 $HRLD_{50}$ ($8.4 \times 10^{4} \times 0.03$) then enters the biological containment suite duct system where it passes through a Baggy Filter (95% efficiency). Consequently, a maximum of 1.3 $HRLD_{50}$ (25.2 x 0.05) is discharged out of the exhaust stack. Within inches of

the exhaust stack, the toxin undergoes infinite dilution in the atmosphere as well as rapid physical degradation. Thus, this concentration of toxin released through the exhaust stack would quickly become negligible.

The third MCE scenario involves the Rift Valley fever virus (RVFV). In this hypothetical event, four 250-ml centrifuge tubes are filled with 240 ml each of a viral culture containing 1×10^9 plaque forming units (PFU) of viral particles per ml, or 9.6×10^{11} PFU total ($1 \times 10^9 \times 240 \times 4$). For mice (C57B16 inbred or ICR outbred strains), one ID_{50} (dose at which 50% of exposed mice become infected) is equivalent to one PFU. The centrifugation occurs in a Class II BSC within a BSL-3 biological containment suite. All four centrifuge tubes break during centrifugation, and a viral aerosol is generated within the rotor of the centrifuge. Most (99%) of the solution is contained within the covered rotor. Of the 1% of the solution released into the centrifuge cabinet, less than 1% becomes aerosolized. Of that which aerosolizes within the centrifuge cabinet, 90% settles as liquid droplets on the inside of the chamber.

Assuming 0.01% aerosolization efficiency, 0.096 ml ($0.0001 \times 240 \times 4$) of the viral culture solution would be aerosolized into 1 to 5 micron particles. This volume corresponds to 9.6×10^7 PFU ($0.096 \times 1 \times 10^9$ PFU). The human respiratory infective dose of RVFV has never been determined or estimated; however, this MCE assumes that humans and mice are equally sensitive and that one mouse ID_{50} (IPFU) is the equivalent of a human respiratory ID_{50} ($HRID_{50}$). Essentially all of this aerosol would be contained within the Class II BSC and exhausted through its HEPA filter (99.97% efficiency at 0.3 micron particle size), thereby reducing the aerosol to 2.9×10^4 $HRID_{50}$ ($9.6 \times 10^7 \times 0.0003$). The aerosol is subsequently exhausted through the duct system of the biological containment suite, thereby passing through another filter (Baggy Filter at 95% efficiency or HEPA at 99.97% efficiency). Thus, a maximum of 1,450 $HRID_{50}$ ($2.9 \times 10^4 \times 0.05$) is vented out of the exhaust stack. At 1 meter or less from the stack, there would be less than one $HRID_{50}$ air which would not constitute a risk to the community.

Because laboratory work is normally performed during the day, it is estimated that ultraviolet rays from the sun would destroy or inactivate a large number of the organisms potentially released during either scenario. Other meteorological variables such as high wind speed, low humidity and/or high temperatures would further accelerate biological decay of infectious particles. Laboratory personnel who work with etiologic agents are protected by vaccination when available, and they should not be exposed since the aerosol should be contained within the BSC, but would receive appropriate medical care immediately (e.g., antibiotic therapy in the case of bacterial agents) in the event of such potential exposures. Because there are no dwellings adjacent to the property, it is concluded that the MCEs would not pose significant risks to the community.

5.2.11 Environmental Justice

Executive Order 12898, *Federal Actions to Address Environmental Justice in Minority Populations and Low Income Populations*, requires Federal agencies to consider whether their projects will result in disproportionate adverse impacts on minority or low income populations. The U.S. Census defines the poverty level as the income level, based on family size, age of householder, and the number of children under 18 years of age that is considered too low to meet essential living requirements without regard to the local cost of living. The U.S. Census

considers a poverty area as an area in which at least 20% of the population live below the poverty level.

It is highly unlikely that implementing the proposed action (Alternative I, no action) would result in significant adverse environmental impacts in the areas adjacent to USAMRIID. According to 1990 census tract data, the areas adjacent to these facilities are not poverty or minority areas. Implementing Alternative I (no action) will not result in disproportionate adverse impacts to minority or low income populations.

Similar to Alternative I (no action), implementation of Alternative II is unlikely to have a disproportionate adverse impact on minority or low income populations because implementing Alternative II is not expected to cause significant adverse impacts to air quality, noise levels, aesthetics, transportation systems, odors, utilities, energy supplies, waste generation, or historic or cultural resources. Implementing Alternative III would eliminate the potential for any adverse impacts.

5.3 Cumulative Impacts

The CEQ regulations implementing NEPA define cumulative impacts to the environment as those effects resulting from the impact of the proposed action when combined with past, present, and future actions (40 CFR 1508.7). Thus, cumulative impacts are the sum of all direct and indirect impacts, both adverse and positive, that result from the incremental impacts of the action when added to other past, present, and predictable future actions regardless of source. Cumulative impacts may be accrued over time and/or impacts in conjunction with other pre-existing effects from other activities in the area (40 CFR 1508.25).

No negative cumulative environmental impacts have been observed from the conduct of activities similar to the proposed action at USAMRIID to date. It is highly unlikely that cumulative adverse environmental impacts will result from implementing the proposed action (Alternative I, no action) because the current and currently planned activities are of a scale that will be readily accommodated by existing facilities and utilities. No construction or renovation is planned. Contributions of the proposed activities to local or regional waste streams or resource utilization will be negligible.

Implementing the proposed activities at another facility (Alternative II) is also unlikely to produce significant cumulative impacts because the amounts of wastes and resource utilization would be small. Implementing Alternative III will eliminate the negligible to minor adverse cumulative impacts associated with implementing the proposed action.

5.4 Comparison of the Proposed Action with the Alternatives

5.4.1 Alternative I – Continue Current and Currently Planned Activities at USAMRIID – No Action

The laboratory methods, facilities, hazardous materials, safety, and biological containment practices used in the conduct of the proposed activities involving the use of biological defense

products are consistent with those required and employed at other biomedical institutions performing similar work (DA, 1989; CDC/NIH, 1999). The potential for adverse impacts to the human environment resulting from the conduct of the proposed activities is extremely small. Positive impacts to U.S. civilian populations and the military are likely.

5.4.2 Alternative II – Conduct Some or All of the Current and Currently Planned USAMRIID Activities at Another Facility

Similar to Alternative I (no action), conducting the proposed USAMRIID activities at another facility (Alternative II) is likely to result in minor or negligible impacts to the environment unless renovation or new construction is required at the site. Implementation of Alternative II does not offer any advantage over Alternative I (no action).

5.4.3 Alternative III – Cease Current and Currently Planned Activities at USAMRIID

Alternative III entails not conducting the proposed USAMRIID activities. Implementing this alternative would eliminate the potential negligible adverse impacts associated with the proposed action. This is not preferred, however, because it would also eliminate the potential positive impact to efforts toward medical defense against validated biological warfare threats and infectious diseases.

6.0 CONCLUSIONS

The most severe potential effects associated with the proposed action are predicted to be negligible, and, to date, all quantifiable impacts associated with similar activities at USAMRIID have been insignificant. Potential risks to human health and the environment will continue to be mitigated by applying required standards, practices, and controls pertaining to the safe use and disposal of hazardous biological and chemical materials, the protection and conservation of natural resources, and the safe and ethical conduct of laboratory and animal studies.

The principal conclusions of this EA are: (1) continuing current and currently planned activities at USAMRIID (Alternative I, no action, the preferred alternative) is not expected to result in significant adverse environmental impacts; (2) implementing the preferred alternative will likely result in important benefits to the U.S. by contributing to medical defense against validated biological warfare threats and infectious diseases; (3) conducting some or all of the current and currently planned USAMRIID activities at another facility (Alternative II) is not likely to alter the negligible to minor potential for environmental impact and does not offer significant advantage over the preferred alternative; and (4) ceasing current and currently planned activities at USAMRIID (Alternative III) will eliminate the negligible environmental impacts associated with the proposed action but will also impede U.S. efforts toward medical defense against validated biological warfare threats and infectious diseases.

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10.0 ACRONYMS AND ABBREVIATIONS

°F	degrees Fahrenheit
AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care
ABSL	animal biosafety level
AR	Army Regulation
BDRP	Biological Defense Research Program
BDRP FPEIS	Biological Defense Research Program Final Programmatic Environmental Impact Statement
BSC	biological safety cabinet
BSL	biosafety level
C	carbon
CAA	Clean Air Act
CDC	Centers for Disease Control and Prevention
CEQ	Council on Environmental Quality
CFR	Code of Federal Regulations
CHP	Chemical Hygiene Plan
CO	carbon monoxide
COMAR	Code of Maryland Regulations
Cr	chromium
DA	Department of the Army
DHHS	U.S. Department of Health and Human Services
DIS	Directorate of Installation Services
DNA	deoxyribonucleic acid
DoD	Department of Defense
DRMO	Defense Reutilization Marketing Office
DTRA	Defense Threat Reduction Agency
EA	Environmental Assessment
EPG	Environmental Planning Guide
FDA	U.S. Food and Drug Administration
FSP	Facility Safety Plan
FY	Fiscal Year
GLP	good laboratory practices
H	hydrogen
HEPA	high-efficiency particulate air
HID_{50}	dose which infects 50% of humans exposed
HQ	Headquarters
$HRID_{50}$	dose which infects 50% of humans with respiratory exposure
$HRLD_{50}$	dose which causes death in 50% of humans with respiratory exposure
HUC	Human Use Committee
I	iodine
IBC	Institutional Biosafety Committee
ID_{50}	dose at which 50% of those exposed become infected
In	indium
IND	Investigational New Drug
INRMP	Integrated Natural Resource Management Plan
IP	Intraperitoneal

kWh	kilowatt hour
l	liter
LACUC	Laboratory Animal Care and Use Committee
LAI	Laboratory-acquired Illness
LARF	Large Animal Research Facility
LD_{50}	lethal dose which causes death in 50% of those exposed
LSS	Laboratory Sewer System
M	mouse
ml	milliliter
MCE	maximum credible event
MCi	millicurie
MCL	maximum contaminant level
MDE	Maryland Department of the Environment
$MIPLD_{50}$	dose which causes death in 50% of mice injected IP
MOA	Memorandum of Agreement
MSDS	Material Safety Data Sheet
Na	sodium
NAAQS	National Ambient Air Quality Standards
NEPA	National Environmental Policy Act
Ni	nickel
NIH	National Institutes of Health
NOx	nitrogen oxides
NPDES	National Pollutant Discharge Elimination System
NRC	U.S. Nuclear Regulatory Commission
NRHP	National Registry of Historic Places
O_3	ozone
OSC	Operational Services Command
OSHA	Occupational Safety and Health Administration
P	phosphorus
Pb	lead
PCE	tetrachloroethylene
PFU	plaque forming units
PL	Public Law
$PM_{2.5}$	particulate matter less than or equal to 2.5 microns in aerodynamic diameter
PM_{10}	particulate matter less than or equal to 10 microns in aerodynamic diameter
PPE	personal protective equipment
RDT&E	research, development, test and evaluation
RMP	Risk Management Plan
RPO	Radiation Protection Officer
RVFV	Rift Valley fever virus
S	sulfur
SAIC	Science Applications International Corporation
SIP	Special Immunizations Program
SO_2	sulfur dioxide
SOP	standard operating procedure

SRPO	Safety and Radiation Protection Office
SSP	Steam Sterilization Plant
TAP	toxic air pollutant
TCE	Trichloroethylene
USAEC	U.S. Army Environmental Center
USAG	U.S. Army Garrison
USAMRICD	U.S. Army Medical Research Institute of Chemical Defense
USAMRIID	U.S. Army Medical Research Institute of Infectious Diseases
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	U.S. Code
USDA	U.S. Department of Agriculture
USEPA	U.S. Environmental Protection Agency
USFWS	U.S. Fish and Wildlife Service
USGS	U.S. Geological Survey
VOC	volatile organic compound
VMD	Veterinary Medicine Division
WRAIR	Walter Reed Army Institute of Research
WWTP	wastewater treatment plant

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APPENDIX A

USAMRIID Safety Regulations Contained in the *Safety Program Manual*

USAMRIID Regulation 385-14, 3 June 1991, *Safety Program*.

USAMRIID Regulation 385-1, 1 November 1990, *Needles, Syringes and Other Sharp Objects*.

USAMRIID Regulation 385-2, 19 June 1998, *Decontamination of Equipment and Materials Using Paraformaldehyde*.

USAMRIID Regulation 385-3, 1 November 1990, *Microbiological Safety*.

USAMRIID Regulation 385-4, 1 November 1990, *Institutional Biosafety Committee*.

USAMRIID Regulation 385-5, 1 June 1995, *Registration, Control and Deregistration of Etiological Agents*.

USAMRIID Regulation 385-6, 1 November 1990, *Autoclave and Waste Management Procedures*.

USAMRIID Regulation 385-7, 3 February 1997, *Biological Safety Cabinet and Chemical Fume Hood Monitoring and Certification Program*.

USAMRIID Regulation 385-8, 1 December 1990, *Removal of Non-human Primates from Biocontainment Suites*.

USAMRIID Regulation 385-9, 1 December 1990, *Biosafety Level 2 Operations*.

USAMRIID Regulation 385-10, 25 November 1997, *Disposal of Chemicals*.

USAMRIID Regulation 385-13, 3 April 2000, *Shipment of Materials*.

USAMRIID Regulation 385-29, 29 December 1999, *Hazard Communication Program*.

USAMRIID Regulation 385-40, 2 January 1991, *Accident/Illness/Incident of Potential Hazard Exposure, Reporting, Records, and Investigation*.

USAMRIID Regulation 385-69, 1 March 1995, *Biocontainment Laboratory Operations (Biosafety Levels 3 & 4)*.

USAMRIID Regulation 385-70, 15 March 1996, *USAMRIID Emergency Preparedness Plan with Change 1 issued 12 March 98*.

USAMRIID Regulation 385-30, 29 November 1999, *Chemical Hygiene Plan*.

USAMRIID Regulation 385-11, 20 May 1992, *Health Physics Regulation for Utilization of Ionizing Radiation*.

USAMRIID Regulation 385-15, 20 June 1992, *Respiratory Protection Program*.

USAMRIID Regulation 385-16, 16 October 1998, *Bloodborne Pathogens Exposure Control Plan*.

USAMRIID Regulation 385-17, 19 February 1999, *Decontamination of Containment Areas with Paraformaldehyde*.

USAMRIID Regulation 385-68, 15 April 1998, *Class III Biological Safety Cabinet and Glove Box Monitoring and Field Certification Program*.